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A New Hope: Automated Bag Breathing Unit

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A New Hope: Automated Bag Breathing Unit

by

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Dedicated to the ABBU Team, who spent countless hours volunteering for this project.

Acknowledgments

I would like to thank my wife, Sara, and son, Liam, for working so hard to let me make all the daily morning calls and give me time to work on this project. With the vaccines being distributed, COVID might finally be coming to a close. Though ABBU might not have made a difference in the clinic, it was our best effort to help the world when we all felt helpless. For that I am proud to have worked on it and write about the engineering effort it took to realize.

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The University of Texas at Austin
May 2021

A New Hope: Automated Bag Breathing Unit

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The University of Texas at Austin, 2021

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This thesis covers the electronics and software used to control a low cost ventilator designed to meet the demanding needs of severe COVID patients.

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Chapter 1

Rise of COVID-19

1.1 History of COVID-19

On December 26, 2019, a 41 year old man was admitted to the Central Hospital of Wuhan with with a cough, fever, and tightness of chest during the first week. Computed Tomography scans and chest radio-graphs showed some abnormalities in the lower lung region which prompted tests for known respiratory diseases. The patient kept testing negative for known respiratory diseases: influenza, *Chlamydia pneumoniae*, and *Mycoplasma pneumoniae* [7].

The patient worked at seafood wet market and claimed no contact with poultry, which may have pointed to the severe acute respiratory syndrome coronavirus (SARS-CoV), which was identified in China in 2003. Further DNA sequencing by Wu et al. revealed that the patient hosted a previously unknown coronavirus (CoV), with aproximately 76% amino acid similarities shared with SARS-CoV [7].

By the middle of February 2020, China had reported 72,314, both suspected and confirmed with the new COVID-19. Of the 44,672 confirmed individuals, 2,087 were deemed critical. Of the critical patients, 49% eventually proved fatal [8]; an overall fatality rate of 2.3%. Wu went on to analyze the severe confirmed cases which suffered from labored breathing (dyspnea), high respiratory rate $\geq 30/min$, blood oxygen saturation $\leq$ 93%, and low partial pressures of arterial oxygen to fraction of inspired oxygen $\leq$ 300. Cases labeled critical also suffered from the severe symptoms in addition to respiratory failure, septic shock, and multiple organ dysfunction / failure.

On March 11, 2020, the World Health Organization declared COVID-19 a global pandemic and by April 4th, COVID-19 had spread to 203 countries, and infected 1.2 million people. Of these, approximately 65,000 had died, and 264,000 had recovered [4]. Of the 1.2 million confirmed cases, over 300,000 were reported in the US, mostly in New York. Due to the rapid spread of the disease, hospitals were at risk to quickly run out of critical care beds and ventilators needed to treat the critically ill and severely impacted patients.

1.2 Engineers and Medical Doctors Respond to COVID-19

The lack of ventilator equipment to treat critical and severe COVID-19 patients led the Food and Drug Administration (FDA) to issue an Emergency Use Authorization Act (EUA) on March 24, 2020, with a call for ventilator equipment [5]. Under normal circumstances, companies may wish to produce a product that is "functionally equivalent" to an existing piece of equipment. This requires the functionally equivalent product to be approved by the FDA through a process called a 510k before the functionally equivalent product can be offered in the market. The EUA is a grant for new equipment designs that do not have to go through the full 510k process; this "call to arms" for engineers spawned numerous efforts to develop low cost ventilators, 3D printed masks, and other essential components for front- line medical workers from engineers who would not normally attempt a *de novo* or 510k medical device submission.

About the same time as the EUA was released, Dr. Thomas Milner was tapped by the Beckman Laser Institute and Medical Clinic at University of California Irvine as the new Director. Through his new roll, he was introduced to Dr. Brian Wong and Dr. Govind Rajan, whom were trying to build a consortium for a low cost, open source ventilator that was based around an Ambu bag (Figure 1.2). The Ambu bag is a brand of resuscitator, but it also is an acronym for, "Artificial Manual Breathing Unit", and it does just that: a bag that can be hand compressed to provide oxygen to a patient in an emergency setting. Using an AMBU bag as the core of the device would allow for an easily replaceable, universally common core component for a low cost ventilator. The goal of the consortium was to determine the best way to mechanically compress the bag so that a human operator is not required to always accompany the patient.

Many ideas were investigated by numerous groups, and for over a month every evening the consortium would meet virtually and discuss various options for optimal Ambu bag compression. Groups from Virgin Orbital, University of California - Irvine, and the University of Texas were members of the consortium, but other groups, such as MIT, were also spearheading efforts to turn an Ambu bag into an emergency ventilator.

In the end, dozens of AMBU bag based mechanical ventilators were con-

Figure 1.1: Typical Ambu bag device

structed, though few were tested on the humans and animals, as the FDA EUA does not require this.

1.3 A Pressure Source Ventilator?

In electrical engineering, it is common to either have a current source or a voltage source. In a current source, current is the fixed parameter and voltage can change depending on the circuit load. The same is true with a voltage source except voltage is the fixed parameter and current can vary as demand changes. When dealing with fluids, the same concept applies, except voltage and current are interpreted as pressure and flow. For example, the water coming out of a hose is dictated by the water pressure, and the flow rate can change as the loading of the hose changes. Contrast this with a flow source, for example a desk fan. The desk fan is flowing a fluid (in this case, air) with a fixed rate through the blades. Regardless of what is on the other side of the fan, the rotor blades will push so much air per second through the fan chamber.

Typical ventilators are considered flow sources, that is a doctor will set a certain oxygen flow rate and the ventilator will provide it, with the pressure in the patients lungs varying. An Ambu bag based device is a pressure source: a certain external force is applied to the bag, which produces a pressure. This may seem like

a subtle difference, but to provide a consistent "flow" to the patient that an ICU doctor is used to requires some non-trivial Ambu bag compression options.

There are several variables that can be controlled on an Ambu bag to vary the amount of air delivered: how hard the bag is pressed, the duration of the bag depression, and the frequency in which the bag is compressed. Several of the other Ambu bag groups only accounted for two or these variables. In the case of the Virgin ventilator, arguably one of the more notable and widely publicised early designs, used a cam that only accounted for how many times the bag is pressed with the other two variables fixed to each other via the cam shape.

1.4 Breathing Circuit

Much effort was spent on the breathing circuit, the airway and components that connects the patient to the ABBU. Though beyond the scope of this thesis, it should be noted that the ABBU would come packaged with and required to be used with certain section of medical grade tubing and one way valves and COVID capture filters.

1.5 Patient Assist

A ventilator should help augment a patient's breathing efforts and provide help when the patient is not able to inspire sufficient oxygen. If the ventilator is trying to provide air while the patient is exhaling this can be detrimental to the patient and may even cause lung damage. Early attempts from other groups **DID NOT** provide this critical feature, a so called **patient assist** mode.

While other groups raced to get their designs to market, we worked hard to ensure that the ABBU would interface well with the patients and not damage their lungs. Furthermore, this feature was tested *in vivo* in a porcine animal model to demonstrate the effectiveness of the algorithm and hardware, above and beyond other early efforts.

1.6 FDA Approval

Ultimately, the FDA has power over whether the ABBU would be used to help COVID patients. The hardware design , software documentation, and initial porcine data was submitted to the FDA on June 29th of 2020 in the form of an Indication For Use, or IFU. A response was received from the FDA on August 31st with some concerns regarding the breathing circuit and requesting some clarification of porcine data. This required re-running some porcine experiments, but the response to the FDA was submitted on October 14th of 2020, where the ABBU is still waiting on approval, as of of January 2021.

Chapter 2

University of Texas Strikes Back - ABBU

2.1 Guerilla Engineering

Before diving into the design, it is important to set the stage for how the project evolved, as it guided some of the early choices that propagated through the entire project. As the project crystallized and moved into the final phases, there were certainly things that would have been nice to have done differently early on. This project, as envisioned in the early days of the consortium meetings, was planned to be an open source device that could be manufactured anywhere with nearly universal parts. From windshield wiper motors to Arduino microcontrollers, early design choices were specifically intended to be easy to get and reliable, not necessarily the best choice for a medical device.

Most electrical engineers will probably say, why an Arduino? Why not a custom embedded chip for a couple of dollars? Other engineers may ask, why a wiper motor? These choices were driven by the "Cheap - Fast - Right" axiom in engineering. In our case, fast and cheap were the critical choices, as the epidemic was ripping through New York during the early stages of the ABBU project. It would have taken too long to realize a custom embedded PCB solution, as well as going counter to the design goals we touted early on that the device need be able to be made anywhere by almost anyone. Since my work was on the embedded system and PCBs, I would like to specifically address the choice of embedded systems.

The original microcontroller was an Arduino Mega2560, which hosts an Atmel ATmega2560 8-bit microcontroller. This is a fairly ubiquitous microcontroller board, which can be sourced almost anywhere in the world. This met the needs of the early project, until patient assist congealed from a request to a requirement. The final design uses an Arduino Due, which runs a much more modern Atmel ARM Cortex-M3 32-bit processor and is also fairly common. Switching embedded systems seems like a natural point to reduce the cost of goods and move to a custom solution, however at this point in the project the PCBs had already been sized and made for an Arduino board, so the group decided to continue down the Arduino path.

2.2 Shifting Needs - A Product Emerges

As the project progressed and industry and clinical partners were brought on board, it became clear we needed to shift the design mentality from an open source, plans

for anyone to a more gated approach with more thorough testing. Reports from clinical on the consortium calls were coming out that other EUA ventilators weren't being used because of limited feature sets, difficulty to use, and no patient assist mode. These setbacks to earlier projects were taken to heart and delayed the release of ABBU.

This additional time gave our industry partner, Thermotek, time to make much needed industrial and manufacturing improvements to the device: easier cable management, notification stickers and labels, more robust mechanical designs, and helping with some of the FDA testing. On the software side, this additional time was spent working on the patient assist mode. Dr. Johnathan Valvano and Dr. Nitesh Katta, with the help of Dr. Steven Derdak, worked closely and for many hours collecting data and iterating an effective patient assist feature which many of the EUA ventilators did not have and could result in lung injuries.

Ultimately it took longer for the ABBU to come to market, but the team felt that not only should ABBU be low cost, but also useful and not sitting around collecting dust.

2.3 Meet the Team

This project was a monumental undertaking and every single member of the team participated without any monetary compensation. We worked ABBU into our schedules and juggled other jobs and duties while still trying to make difference in the COVID-19 landscape. This work could not have been possible with such a dedicated team. Below is a summary of their contributions, as written by each.

2.3.1 Dr. Thomas Milner

Tom started the project in mid-march. Early discussions with Brian JF Wong at UC Irvine converged and reinforced the belief that a COVID-19 pandemic could result in a ventilator shortage in the United States. The decision was made to start constructing a bridge ventilator device. Engineering team members who immediately became involved included, Arnold Estrada, Scott Jenney, Nitesh Katta, Austin McElroy, and Tim Phillips. Early on the ABBU team participated in daily Bridge Ventilator Consortium calls at 5PM Central Time. As two or three other groups also participating in the BVC, were working to design and build a ventilator

device, daily reports at the BVC developed into a competitive dimension on who could produce a working prototype. The Austin ABBU engineering team emerged as the leader in realizing a prototype ventilator device. The name ABBU was first suggested by Scott Jenney as an acronym for Austin Bridge Breathing Unit.

2.3.2 Dr. Nitesh Katta

2.3.3 Scott Jenney

Scott started the development of an automated breathing medical device by trying different approaches for artificial respiration. Scott worked with the ABBU team and decided that using an AMBU bag would be the easiest and lowest cost solution. He determined the elements and production processes along with integrating workers and assigning tasks. When he got the first prototypes together, biology, medicine and engineering improvement changes were necessary and incorporated in the final design. When the product designs were finalized Scott coordinated with contract manufacturers, suppliers and distributors for product streamlining.

2.3.4 Dr. Tim Phillips

This team member did not respond. Dr. Phillips was the key CAD engineer and worked closely with Robert LaSalle to realize ABBU as a device.

2.3.5 Dr. Aleksandra Gruslova

Dr. Gruslova, Senior Research Scientist at UT Health San Antonio, joined the ABBU team in February 2020, when the simple idea of using motor lever arms to automate operation of AMBU bags was proposed in response to ventilator shortage due to COVID-19. During the first stage of development, Dr. Gruslova assisted in writing grant proposals and ordering supplies.

When the ABBU prototype went through initial bench testing, Dr. Gruslova worked on in vivo testing to prove the safety and efficacy of the device on large animals. Her duties included conducting animal experiments and collecting and analyzing the data. This work was necessary to prove the concept, make engineering adjustments, and develop the final design.

In addition to animal studies, Dr. Gruslova coordinated usability studies, designed the questioner, administered the test, and evaluated results which were incorporated into the EUA for FDA approval of the device. Breathing circuit assembly instructions, ABBU setup, and operation instructions were tested by students enrolled in the respiratory therapy training program (UTHSCSA).

Dr. Gruslova summarized the results of the project and presented ABBU at the 50th Critical Care Congress.

2.3.6 Dr. Van Truskett

This team member did not respond. Dr. Truskett worked to secure partnerships with ThermoTek and managed the FDA process.

2.3.7 Dr. Jonathan Valvano

This team member did not respond. Dr. Valvano was key in writing the patient assist algorithm and implementing the alarm code inside the ABBUAlarm wrapper class.

2.3.8 Dr. Steven Derdak

This team member did not respond. Dr. Derdak drove the requirements for the patient assist and breathing circuit, as was key in ABBU data collection and navigating FDA responses.

2.3.9 Robert LaSalle

Robert LaSalle is a certified EIT in the State of Texas and the Director of Mechanical Engineering at ThermoTek, Inc. He joined the project in late March 2020 as a manufacturability/productionization and industrial design advisor to help evaluate, guide and optimize early 3D CAD designs so that later versions could be quickly and reliably prototyped and manufactured within economically feasible costs and timeframes. He evaluated and selected production custom component fabrication/-manufacturing partners. Throughout the project he collaborated with electrical, mechanical, software, manufacturing, clinical, and regulatory teams to ensure the manufactured product would meet and/or exceed project requirements. He selected

and sourced all production components and accessories of the system (e.g. rolling cart, external power supply, hardware, hinges, handles, and custom components) and designed the interface bracket that enables rolling cart use. He curated the production 2D/3D CAD database, created all the custom mechanical 2D drawings, and defined the production CTQ dimensions. He guided the definition and transfer of design control documents and specifications from the UT team to the ThermoTek QMS. Assigned each orderable component in the system a ThermoTek part number and built up production BOM's per ThermoTek QMS SOP's. He updated the overall mechanical design of the actuation arm as well as the silk-screened radial pattern on the arm that the system uses to encode position of the actuation arm. He helped design, build and test the beta prototypes that were used for the FDA EUA submission. He defined and guided the design of the shipping box and foam for the production device. He did the graphic design of the logo for the production device. He suggested a way to reset devices that have been locked by software by setting the potentiometers to certain settings at startup. He guided the mechanical layout and overall shape of the PCBA. He defined the location of production system components and the order of assembly. Based on the beta prototype build, he defined and implemented mechanical updates to the production build of the system. He defined the cable harness routing for the production system. He defined the build instructions and designed production fixtures for installing components and labels for the production device.

2.3.10 Dr. Arnold Estrada

This team member did not respond. Dr. Estrada lead early efforts to get ABBU up and running before leaving the University of Texas in early 2020.

2.3.11 Dr. Aydin Zahedivash

Aydin joined the ABBU team during the early stages of design. Serving as the bridge between the clinical, testing, regulatory, and engineering teams, he helped refine the ABBU design and operation to best fit the needs of critically ill patients. Throughout the process, he helped hone the design requirements to conform to necessary medical device safety measures. As the ABBU design matured, Aydin helped start and assemble the regulatory team to prepare the device for FDA Emergency

Use Authorization review.

2.3.12 Dr. Marc Feldman

This team member did not respond. Dr. Feldman contributed resources and staff to the ABBU project through Giles and Dr. Gruslova.

2.3.13 Andrew "Giles" Cabe

This team member did not respond. Giles assisted Dr. Gruslova in performing the porcine animal experiments.

2.3.14 Ronit Kar

This team member did not respond. Ronit was an undergraduate student and helped in distilling the software into flow charts.

Chapter 3

ABBU Hardware

3.1 Hardware Overview

The original concept that emerged in the first weeks of the ABBU project was to acctuate the AMBU bag with a rotary driven weighted arm, which would deliver a pulse of air to the patient. The actuating mechanism would need to operate continuously for at least three days, a fairly arbitrary duration that was determined during the early Consortium calls. As always, a concept that appears simple always has complications.

3.1.1 Evolution of the Actuating Arm

Regardless of the final arm design, the windshield wiper motor was a constant, save for the brand. Thomas Milner computed the power requirements of a healthy lung with the additional resistance of the breathing circuit (Appendix A); around 1.35 Watts per breath. Based on this, Arnold and Scott quickly zeroed in on the Toyota Corolla wiper motor, for both its availability and mechanical power. Scott was able to procure several 2002 wiper motors from a local junkyard, while Arnold was sourcing 2016 wiper motors for a newer, more source-able model. The ultimate model was the Cardone 85-3000 (Appendix B), a DC brushed motor which sells for around $40. The 85-3000 operates at 12 Volts at 2.5 Amps, for an approximate input electrical power of 30 Watts.

Early work on the arm and head was spearheaded by Arnold Estrada, Nitesh Katta, Aydin Zahedivash, Scott Jenney, Tim Phillips, and Thomas Milner. The motor clearly has enough mechanical power to actuate the bag, but how the motor interface with the bag quickly became an important engineering challenge. An AMBU bag is intended to be compressed using a human hand, typically with five fingers and the palm, roughly $.054m^2$ for a typical male hand [3]. Furthermore, the bag is compressed in a C-shaped pattern with circumference of the hand changed and "sliding" over the bag with little friction.

The most obvious and simple solution was just to actuate the AMBU bag with a metal arm attached to the motor. This solution had limited surface area and caused increased bag failures such that it was quickly abandoned. The next approach was a ball at the end of the rod, think tennis ball. This worked better than the naked arm, but the ball could not traverse on the arm and had friction issues against the bag.

The final design used a caster wheel with a rubber "tire". This allows for a larger surface area as well as an arm that can "slide" when interacting with the AMBU bag. This reduces wear on the bag and provides a larger surface area for the arm to interact with the bag, maximizing the amount of volume that can be delivered to the patient.

3.1.2 PCB Design

The PCB was designed to be as easy to manufacture as possible, to keep with the original goals of the project - an emergency device with easy to get parts that could be assembled in any country. In the world of PCBs, this means through hole components, as soldering is much more straightforward compared to surface mount parts.

The design was intended to hold all the electronics, except the PWM board, as well as all of the knobs, speaker, and screen. The PCB was laid out using Eagle Professional from Autodesk.

The layout was straight forward (Figure 3.1), mainly being driven from the mechanical engineering side. The board shape, knobs, screen, speaker, and LEDs were specified by Tim Phillips and Robert LaSalle. All the other design choices were left to my discretion.

The layout did not have any high speed or precision analog signals that needed special routing, impedance matched traces, or special attention to ground plane impedances.

3.1.3 Optical Reflectors

The early phases of the actuating arm were all open loop - the arm is commanded to move forward and backward with no feedback to the microcontroller. The open loop design quickly caused all sorts of issues if the unit wasn't operating in optimal conditions. A few attempts were made to affix an optical encoder wheel to the bolt that secured the arm to the motor, but this was discarded as the the motor screw was not long enough.

Nitesh Katta and Tim Phillips had the idea to paint bands, like zebra stripes, on the arm and use a reflective optical encoder mounted on the chassis to help determine arm location. The OPB745 (Appendix E) was selected. Early implementations

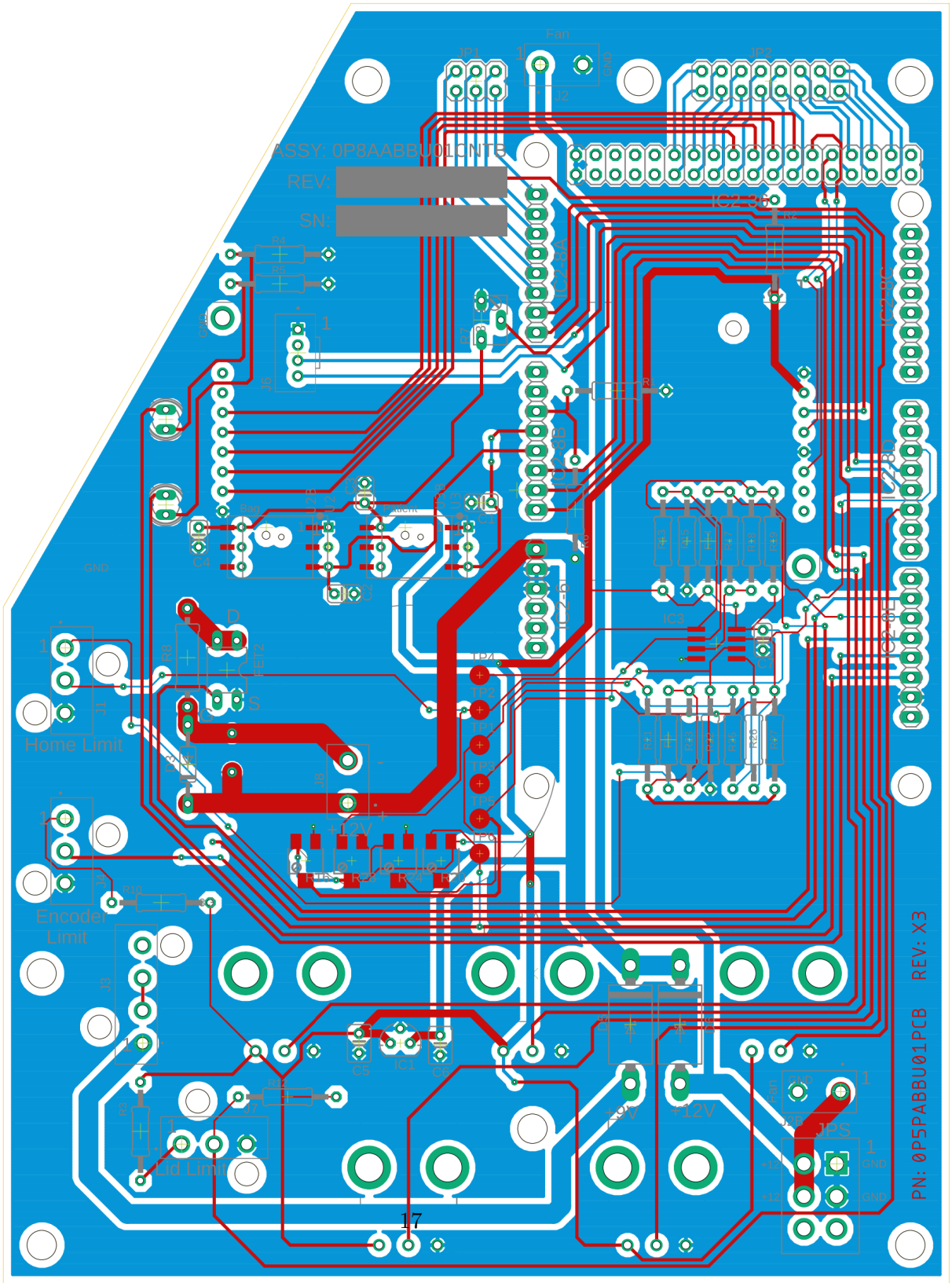


Figure 3.1: ABBU Revision 3 circuit board

of the idea used lines printed on paper, which was good enough to get the concept and prototypes up and running. Robert LaSalle finalized the design by powder coating the zebra stripes onto the arms. It is important to note that some of the early arms used a glossy paint which did not work, as the optical element could not differentiate between white and black gloss. The optical signal needed to be binary, as it was used on the Arduino as a digital interrupt, so it was critical for operation to use a matte paint.

3.1.4 Pulse With Modulation (PWM) Board

The Cardone wiper motor can be run with both positive and negative voltages; with a positive voltage the arm moves forward, with a negative voltage, the arm moves backwards. If the voltage is DC at $\pm$ 12V, the arm would move at a fixed speed. One of the main design constraints was not only the rate at which the patient breaths (Breaths per Minute or BPM), but also the length of the breath (Inspiration) and the speed at which the arm would return to home. To account for all of this, it is necessary to drive the motor with a PWM signal. A PWM signal consists of two parts, the duration or period of the pulses and the duty cycle of a pulse, as seen in Picture 3.2. Regardless of the period, a longer the duty cycle, the faster the motor will operate, until it reaches $\pm$12V. Likewise, regardless of the period, a 0% duty cycle will stop the motor.

Scott Jenney and Nitesh Katta found the Cytron MD13S met the power and voltage requirements of the Cardone motor but were also easy to procure in large quantities. This board also works at both 3.3V and 5V logic levels, which became important when the processors switched from the Arduino Mega to the Arduino Due. Finally, the Cytron MD13S had a large range of periods that it operated over. The Cytron MD13S and Cardone were originally operated using the Arudino PWM library, which has a period of around 1kHz. The Cardone performance was enhanced for a faster period, which required the use of a custom software timer (Section 4.4) instead of the Arduino supplied PWM library. The software timer allows for an interrupt function to be called after a period of time, so the PWM functionality can be extended beyond the 1000Hz PWM supplied by Arduino.

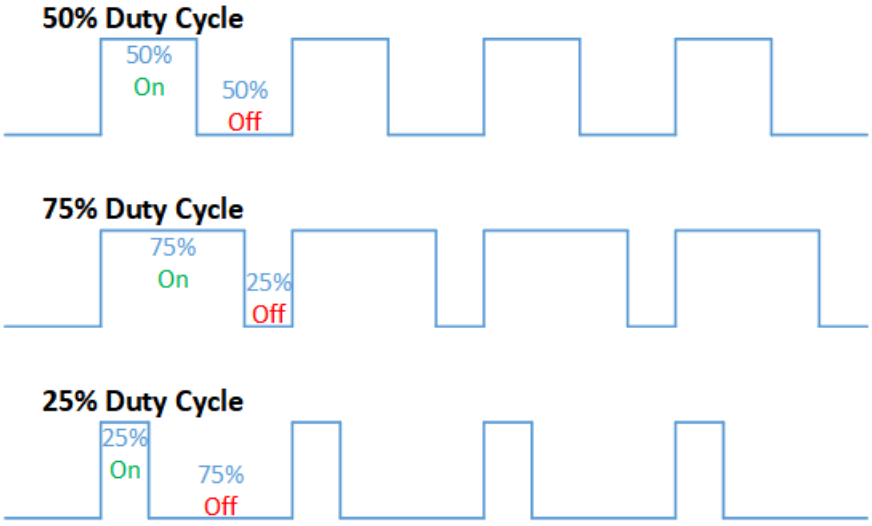


Figure 3.2: Example of a PWM signal of a certain period with varying duty cycles. [6]

3.1.5 Power Supply

The power supply selected was originally going to be a computer power supply. These supplies provide 12V that is easily accessible and even low end computer power supplies typically have at least 180W of power, more than enough for the Cardone wiper motor. As the project moved away from the anyone-can-do-it build as Thermotek became more involved, the team decided to move towards an external medical grade power supply, specifically an FDA approved unit with a strain relief locking mechanism. The final power supply selected was an Inventus MWA220 (Appendix D), a 12V, 220W supply with a 6-pin molex connector that has a lip so the supply can't be accidentally unplugged.

There is also a power switch which is used to cycle the unit off and on. Both the switch and molex power connector can be seen in Figure 3.3.

3.1.6 Pressure Transducer(s)

The pressure transducers are a critical part of the ABBU. With two transducers, it is possible to:

- Detect air way circuit disconnects

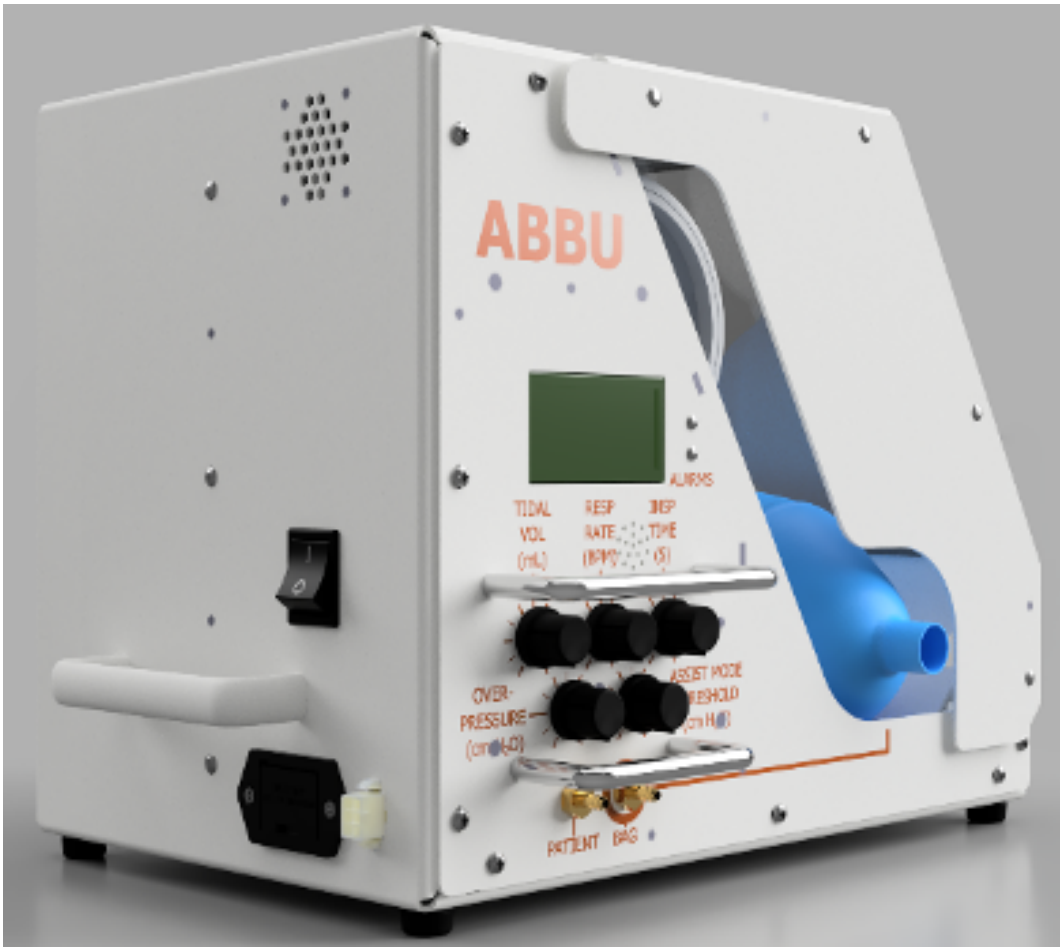


Figure 3.3: Back of ABBU showing the power switch and power input molex connector

- Detect when the patient is trying to breath
- Determine if there is too much pressure being applied to the patient

Scott Jenney selected a non-differential Honeywell sensor from the NBP family with a range of 0 to 1 psi, with a 5V drive voltage. An early idea had been to put two sensors on, so that a flow could be computed, but this ultimately didn't work out because of the breathing circuit. We opted to utilize one sensor for pressure near the patient, and one sensor for pressure near the AMBU bag. This allowed us add an additional patient safety feature that checked for breathing circuit disconnects if the bag pressure dropped to 0 psi.

The drive voltage caused some consternation when the processor was changed from the Arduino Due, as it operated at 3.3V. The solution was a small daughter card that Dr. Valvano designed that allowed the sensor to be run at 5V, but stepped the voltage down such that the maximum voltage into the Arduino Due was 3.3V.

3.1.7 User Input Controls

The ABBU was meant to be easy to use and with a simple user interface. Coupled with feedback from Dr. Derdak, the team ultimately decided on five user input knobs, which can be seen in Figure 3.4. The five knobs controlled:

- Tidal Volume - amount of air volume actuated per cycle.
- Respiration Rate - number of times the arm actuates the AMBU bag per minute
- Inspiration Time - time over which the tidal volume is delivered
- Over Pressure - pressure value deemed damaging to the patient
- Assist Mode Threshold - the pressure limit that would trigger a patient assist breath

Tidal Volume

Tidal volume is the amount of air that can be delivered to the patient per actuation cycle of the arm. This can range from 200mL to 800mL. The upper limit is fixed by the AMBU bag, while the lower limit was derived from Dr. Derdak's input.

Respiration Rate

This is the rate at which one arm cycle completes, ranging from 10 to 40 breaths per minute. Note that this time also includes the inspiration time. Turning this knob all the way to the left stops the arm from moving.

Inspiration Time

The amount of time to deliver the tidal volume. This can be changed from 0.5 to 1.5 seconds and is included in the calculation of the respiration rate.

Over Pressure

This is a pressure setting adjustable between 50 to 70 cmH_2O. If the air pressure at the patient exceeds the over pressure value, the arm retracts. This feature helps prevent damage to the patient's lungs.

Assist Mode Threshhold

This is a pressure adjustable between -1 and -10 cmH_2O. The patient pressure is directed into an algorithm to determine the Peak End Expiratory Pressure (PEEK). If the patient pressure falls below $P_{PEEK} + P_{assist}$, the patient is determined to be trying to draw a breath and a breath is delievered. Setting the Assist to -10 cmH_2O effectively disables the assist feature. This is covered in more detail in Section 4.7.

3.2 Display

The display is a Newhaven NHD-0420H1Z 20x4 character display with a white back light. The display conveys warnings and user input settings as well as some diagnostic information. Figure 3.5 shows the display with labels as submitted to the FDA. The screen was originally a 16x2 display, but it was quickly decided to upgrade. As the project progressed, Dr. Derdak requested more information to be displayed, to match a more traditional ventilator. A larger screen should have been selected, but we were hampered by time and what the Arduino could responsibly drive; to fancy and too many resources are dedicated to running the screen and not the ABBU.

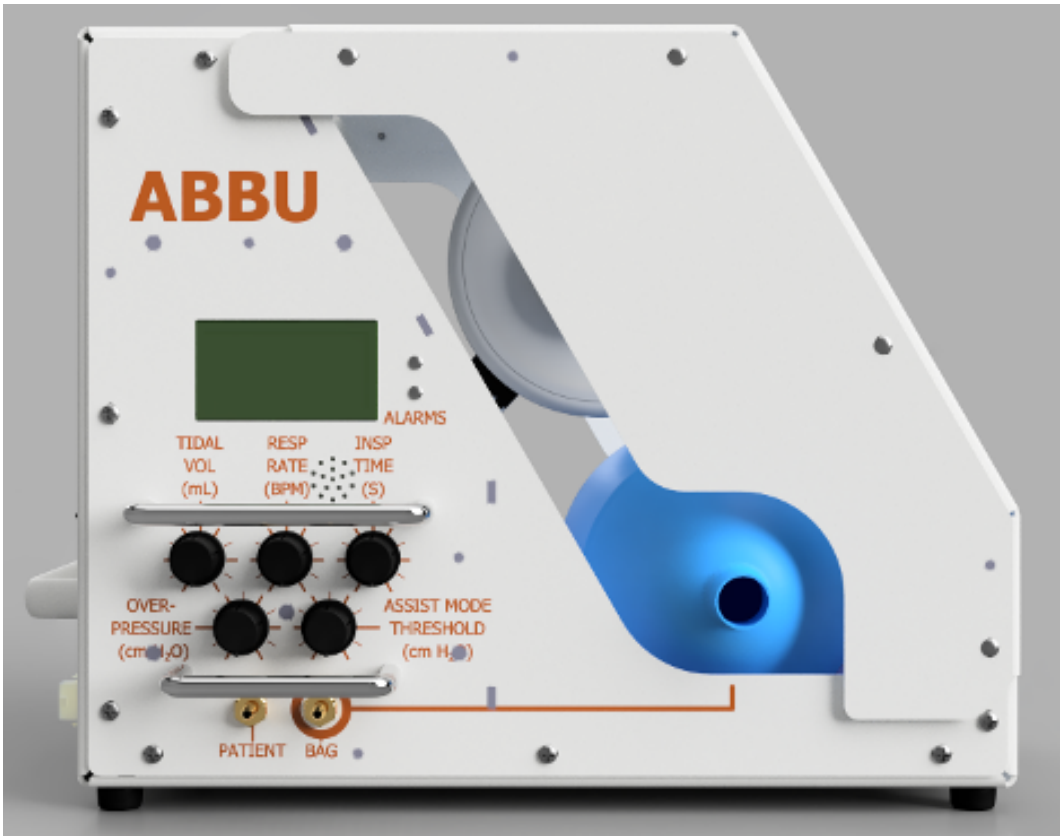


Figure 3.4: Side view of the ABBU with black user intput control knobs.

3.3 Alarms

The ABBU has several outputs to present alarms to the user. There is an audible alarm, one red LED, one blue LED, and the display screen. These alarms are used to indicate notifications, low priority, or high priority alarms. The speaker is the CUI CLF0381MP-1 (Appendix F, which was chosen both for its audible and electrical power. Though we did not have to meet FDA tone and audible power requirements, Dr. Valvano ensured this was the case through rigorous audible power test measurements.

3.4 High Priority Alarms

High priority alarms signal a critical, damaging or life threatening condition. A high priority alarm is indicated by a flashing red LED and an audio alarm of three c notes, a pause, and then two c notes. The alarms will keep notifiying until a corrective action is taken or the ABBU unit turned off. The software implementation can be found in Section 4.3.

Over Pressure

This alarm activates when the patient pressure transducer measure a pressure that is higher than the pressure set using the Over Pressure knob. For example, the patient pressure read 60 cmH_2O and the Over Pressure knob is set to 50 cmH_2O. This could mean the patient or patient breathing circuit has an obstructed airway.

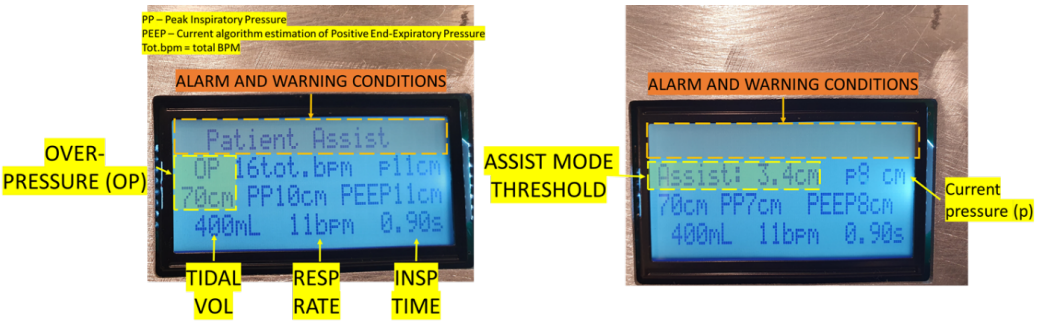


Figure 3.5: Display with data labels, as submitted in the FDA IFU

The user must inspect the breathing circuit and/or the patient for problems or increase the Over Pressure setting to clear the alarm.

3.4.1 Under Pressure

This alarm is almost always tied to an improper breathing circuit. If the bag pressure transducer measures a pressure $< 3cmH_2O$, the alarm will trigger. The corrective action is to check for breaks or leaks in the breathing circuit and the AMBU bag.

3.4.2 Loss of Power

The ABBU is meant to operate from a standard electrical wall outlet, which in the United States is 120V AC at 60Hz. If power is lost, the ABBU arm will cease operation, leaving the patient in a critical state. The ABBU contains a 9V back-up battery that can run the Arduino Due and alarms for several minutes to alert the user that power has been lost. It is critical that power is restored or the patient manually bagged until power is restored. This alarm will clear only after power is restored or the 9V battery discharges. Fortunately, the user or nearby caregiver can lift the lid and manually move the arm to access the AMBU bag for immediate patient resuscitation until power is restored.

The 9V battery **MUST** be replaced as soon as power is restored and the patient is safe, as further power losses on the same battery will lessen the likely hood that the alarm will function as intended. The intended use for a 9V battery is to provide at least 7 minutes of power to the battery and activate the alarm buzzer.

3.5 Low Priority Alarms

These are meant to alert the user to an issue that is probably not critical to the patient, but perhaps should be looked into. Currently there is only one low priority alarm and one notification.

Tidal Volume Out of Spec

This can happen if the tidal volume is very large, but the patients lungs may not be able to handle the actuated air. In this case, the requested encoder count would

not be met, as the arm stalls on the bag. The corrective action is to check for obstructions or reduce the tidal volume.

Motor End of Life

This is a warning that is displayed on top line of the display screen and occurs only if the motor has moved a certain amount of times. The warning is currently set to 7,000,000 arm cycles, but this may be changed. The only way to remove this notification is to send the unit back to the factory to have the motor replaced.

Chapter 4

ABBU Software

4.1 Software Overview

The software to control the ABBU had to handle a myriad of tasks with the ability to add and subtract segments of code without causing a redesign each time. The concept of "Low Coupling, High Cohesion" was employed when the initial architecture was envisioned. The coupling was minimized by having five generic tasks, with each task having minimal cross-talk to the other tasks. Since this was not a threaded environment, global variables were sufficient and we did not employ semaphores or mutexes. Each task could be enabled or disabled, to better isolate issues as code was written. The tasks were scheduled using the Arduino **Scheduler** library, where each time a task was "resting" using the **delay** command, another task would spin up. The task scheduler was limited, in that all tasks had the same importance and tasks could not interrupt each other, as would happen in a proper Real Time Operating System. We discussed using a Real Time Operating System (RTOS) in the early stages, but Dr. Valvano did not think the non-deterministic nature of an RTOS would outweigh the complications of implementation. There is also a vestigial Logging task that was used early and has been turned off at compile time. The five tasks are:

- Pressure Acquisition
- Motor Control
- User input acquisition
- Display
- Alarms

Details of each task are to follow, but a quick overview can be seen in Figure 4.2 and Figure 4.3.

The programming was a mix of C and C++, with C style being preferred, and C++ being used mostly for the **std::string** library and for organizing code into a **class**. Memory was statically allocated at compile time, using the **#define** options in **settings.h**. The goal was to avoid using **malloc** and **free** to avoid long term memory fragmentation and non-determinism.

The programming environment was Microsoft Visual Studio Community with the Visual Micro plugin. Visual Micro provided a clean interface between Visual Studio and the Arduino compiler, GCC 7.3.0. The plugin also provided a **JTAG** interface for programming and debugging the Arduino Due with an Atmel-ICE-C for SAM processors. This was invaluable and the project could not have been completed through typical Arduino debugging techniques such as serial logging.

The pins referenced in the following section are referenced to the Arduino pin map, which is common across almost all Arduino familes with the same footprint. The Due pinout can be found in Figure 4.1, with the labels on the header socket [1]. For example, analog pin 0 for the Respiration control knob is pin A0 on the header, and digital pin 5 for the limit switch encoder is digital pin 10, which is also PWM10, depending on the configuration. Only certain digital pins could be used on the Arduino Mega for digital interrupts, which lead to the original pin selection. On the Due, almost any digital pin can be assigned as a digital interrupt trigger.

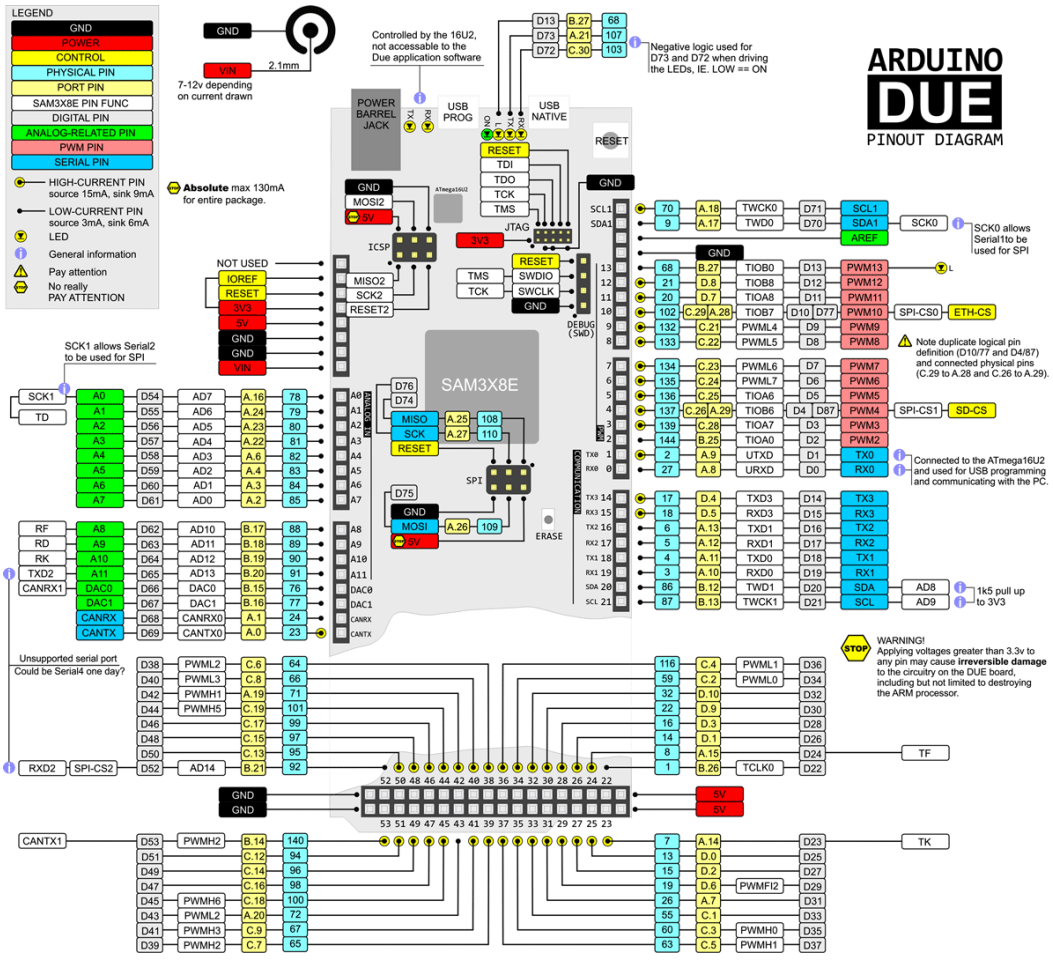


Figure 4.1: Arudino Due header pinout and multiple variations

4.2 Analog Input Acquisition

Several of the tasks were responsible for collecting data from the outside world, either from the user input knobs, the pressure transducers, or the power supply. The data acquisition shared a common set of reusable functions. Each signal input was acquired by one of several 10-bit data acquisition pins mapped to the Arduino analog to digital converters as outlined below:

- Respiration Rate → Pin 0
- Patient Assist → Pin 1
- Inspiration Time → Pin 2
- Bag Pressure → Pin 3
- Patient Pressure → Pin 4
- Voltage Sense → Pin 5
- Over Pressure → Pin 8
- Tidal Volume → Pin 9

The analog input values were acquired using a class call AnalogInput which provided a common platform for analog acquisition and linearly mapping the acquired voltages to physical values. An AnalogInput object creation required the pin that was to be acquired, as well as an optional history_size parameter used for keeping a running history of prior values.

Once the voltage was acquired, it was kept in 10-bit digitally quantized form and had a dead zone applied to it. This is useful for preventing quantization error at either the lowest or highest setting of the potentiometer. ABBU set the acquired value to zero if the quantized voltage was below 32, or maximized the acquired value if the quantized value was above 992. The quantized value was mapped to a physical value using a struct LinearMap, which contains a slope, intercept, and zero_if_below parameters. The zero_if_below variable was used in the case of respiration knob, and provided a way of settings the mapped value to 0 if the quantized count was below a certain value. In production, the zero_if_below count was 128 only for the respiration knob. All of these values can be easily changed in **settings.h**.

Linear maps could be created using the AnalogInput::createLinearMap static method, which could be fed into an AnalogInput object using setLinearMap. On the original Arduino Mega, an 8-bit micro-controller, applying a floating point linear map required a non-trivial amount of CPU time. To minimize the processing time, the linear map was applied only when calling the AnalogInput::acquireMeasurement method, which cached the computed value and could be quickly recalled using AnalogInput::getMeasurement. The quantized value in volts could also be fetched using AnalogInput::getVoltage, which was useful when monitoring the power supply to check for power loss conditions.

4.3 Hardware and Timer Interrupts

There were several time-critical operations of ABBU that required the use of hardware interrupts. These special functions supercede almost all other operations and can be called a few clock cycles after being triggered. The triggering event can happen internally, as is the case with a hardware timer, or externally, as is the case for the optical encoders. The main benefit of interrupts and hardware timers is that they take next to no processing power and the functions tied to the interrupts are only called when the interrupt event happens.

The interrupt related pins are:

- Home Optical Encoder → Digital Pin 2
- Motor PWM → Pigital Pin 3
- Motor Direction → Pigital Pin 4
- Lid Limit Switch → Digital Pin 5
- Arm Optical Encoder → Digital Pin 10
- Alarm Buzzer → Digital Pin 11
- Blue Alarm LED → Digital Pin 12
- Red Alarm LED → Digital Pin 13

An important note about interrupts is that when the interrupt occurs, the CPU registers may or may not hold the values that the interrupt function needs to operate on. When the compiler optimizes code, it can be clever and leave variables in CPU registers, called caching. It is critical that any variable that is used in an interrupt routine be marked *volatile*, so that the compiler can create the proper instructions to pull the value from memory instead of maybe or maybe-not a cached value in a register.

The Arduino Due offers up to nine hardware timers that can be programmed in a variety of ways. The ABBU required several clock sources that had precise timings, ranging from 10's of μS to hundreds of mS. The timers can be accessed via registers, but programmer Ivan Seidel offers the DueTimer package available as an official Arduino library.

4.3.1 PWM Timer and Encoder Interrupts

The most critical timer section is the timer to control the PWM signal to the CytronMD13S. We originally used the traditional AnalogWrite function through the Arduino code, but this proved ineffective and the motor behaved sluggishly due to the 1000Hz maximum PWM frequency.

It was decided to move the PWM to a 10μs time base with a period of 255 ticks per period, for an overall PWM period of 2.5ms (and 10us resolution). The value 255 is an efficient number as it is represented by the uint8_t value that overflows to 0, thus the only value that needs to be updated is the number of ticks high and low. No bounds checking needed.

The main class that interacted with the motor was **ABBUMotor**. This class encapsulated the timer, encoder interrupts, and a digital output to control the direction.

4.3.2 LED Timers

The ABBU has a timer that can be used to blink LEDs, however only the red LED was specified to blink. The blink rate was 2.5Hz when a critical alarm occurs.

4.3.3 Tone Generation Timer

A timer was also used for for tone generation. The timer for this event was tied to the frequency of the tones of C4 and C5, or 261.626Hz and 523.25Hz, respectively. The common base frequency of around 1047Hz was then selected as the rate at which to update the digital pin tied to the speaker.

4.4 Motor Control Task

The ABBU Motor Control Task is probably the most complicated of the tasks and is responsible for all arm related motion, interfacing with patient assist, arm calibration, and disabling the arm. This task was designed as a state machine, after each completion of the task, the state is either changed or maintained as needed. This task also keeps track of how long the state has been running.

Prior to entering the state machine, a few checks are made that may force an override of the prior state decision. These possible overrides are:

- Over pressure - if the pressure reading was measured to be above the set over pressure value, the arm would retract to home and wait for the next breath.
- Motor off - if the respiration knob was turned all the way to the left, the motor would enter an "off" state and move to the home position.
- Patient Assist - if the patient assist algorithm identified the patient trying to breath, the motor would move forward, regardless of the set respiration frequency.

If none of the override conditions were met, the Motor control task would maintain normal operation, moving forward and backward based on the front panel control knobs.

4.5 Monitoring Pressure Task

4.6 Alarm Task

The alarm tasks was a function that called the ABBUAlarm::Update class every 100ms, which is a blocking method. If an alarm was active, the task would loop

every 3 seconds.

4.6.1 ABBUAlarm Class

ABBUAlarm is the code responsible for managing the alarm state and the timers associated with the tone generation and blinking or static LEDs. ABBUAlarm was allotted two of nine hardware timers, one for LED blinking, and one for tone generation.

Alarms were encoded in an unsigned integer number, with each alarm occupying a bit location. This was chosen over a more traditional Queue because it is deterministic and a switch-case statement allows us to rank the alarms in order of priority. Each alarm case was blocking for three seconds, so that only a single alarm can be active at a given time. After the alarm has finished, the bit associated with the error is cleared and the next alarm could be activated. If no alarm was active, there was a built in delay of 100ms.

Any task could add or clear an alarm flag by calling ABBUAlarm::add and ABBUAlarm::clearAlarm. Clearing an alarm from outside the ABBUAlarm::update method was only used in the case of clearing the Watchdog error, covered in 4.10.

4.7 Patient Assist

4.8 Display Task

The display task was responsible for updating the 20x4 character LCD and was the entry point for the ABBUDisplay class. It was set as an infinite loop with a 100ms delay between calls. If the user changed the patient assist knob, the screen had an additional state where it would alternate between the assist pressure setting and the breaths per minute rate.

4.8.1 ABBUDisplay Class

ABBUDisplay was the main interface between the software and the display, using the **LiquidCrystal** library provided by Arduino. Most of the tasks had values that needed to be displayed, but calling the display update functions could impact performance. To avoid this, each task could cache a method variable in ABBUDisplay

that needed to be updated, and the Display task would execute every 100ms and update the display with the cached values. The exception to this was in the case of an alarm. ABBUAlarm::update was allowed to update the first row of the display, which was used only for alarms.

4.9 Flash Storage

Flash storage is a small amount of memory on a processor that is non-volatile which means that flash memory retains its value regardless of the power state of the device. Of course flash memory can only be written to when the unit is powered.

The SAM3X processor offers 512kB of flash memory, divided into program space and user space. The defaults, which were used, are half of the flash for program space and half for user space, which we used to record the motor count (the number of times the motor left and returned to home), how many times a watchdog error occurred, and how many times a watchdog error was reset.

Overall, this amounted to 7 bytes of data recorded, a fraction of the space provided. For the next generation, things like the last several seconds of waveforms and other diagnostic data logging data could be recorded.

4.10 Watchdog Timer

A watchdog timer is a specialized timer, either internal or external, that is periodically reset when software and hardware is running as intended. If the timer is not reset, it usually indicates that an error has occurred and a fail safe action needs to happen. On the SAM3X processor, this functionality runs on separate hardware from the main code loop. If the watchdog timer is not reset, the processors reboots and the software starts over.

For the ABBU, the worst event that could happen is that the user intends the arm to move, and the arm does not move, either it is stuck, detached from the motor, or the motor has failed. This is a critical life threatening event, a perfect use of a watchdog timer. This also makes a natural watchdog reset, whenever the arm found home, the watchdog timer was reset. If the arm was disabled, the watchdog timer was also reset.

A watchdog error occurred if the watchdog timer was not reset after 14

seconds. A status register is checked when the software starts to detect whether the unit was reset due to the watchdog, and if so non-volatile counter was incremented. If this occurred 3 times, the ABBU is "bricked" and can't be used.

Since this may often occur during testing and assembly, a unit could be "unbricked" by setting the input knobs to a certain orientation before the startup code executed. If a unit was "unbricked" this way, a counter was incremented in non-valatile memory and displayed at start up. This way manufacturers could see if units were being reset or improperly used in the field.

4.11 Doxygen Documentation

To quote Doxygen's website:

> Doxygen is the de facto standard tool for generating documentation from annotated C++ sources, but it also supports other popular programming languages such as C, Objective-C, C#, PHP, Java, Python, IDL (Corba, Microsoft, and UNO/OpenOffice flavors), Fortran, VHDL and to some extent D.

What better way to generate software documentation than the de facto standard?

Doxygen is programmed to open a file and look for specifically formated comments, pull them out, and compile them into a monolithic document. This means that the final document is only as good as the comments provided by the programmers. This fell to Dr. Valvano and myself to go through each C pre-processor definition, each class method, and most class variables and create meaningful comments for what the intended use of that function or variable was for.

Once all of the code was commented, Doxygen was configured to generate LaTeXand HTML documentation. The LaTeXdocuments can easily be converted into a PDF, which was submitted to the FDA as part of the EUA package.

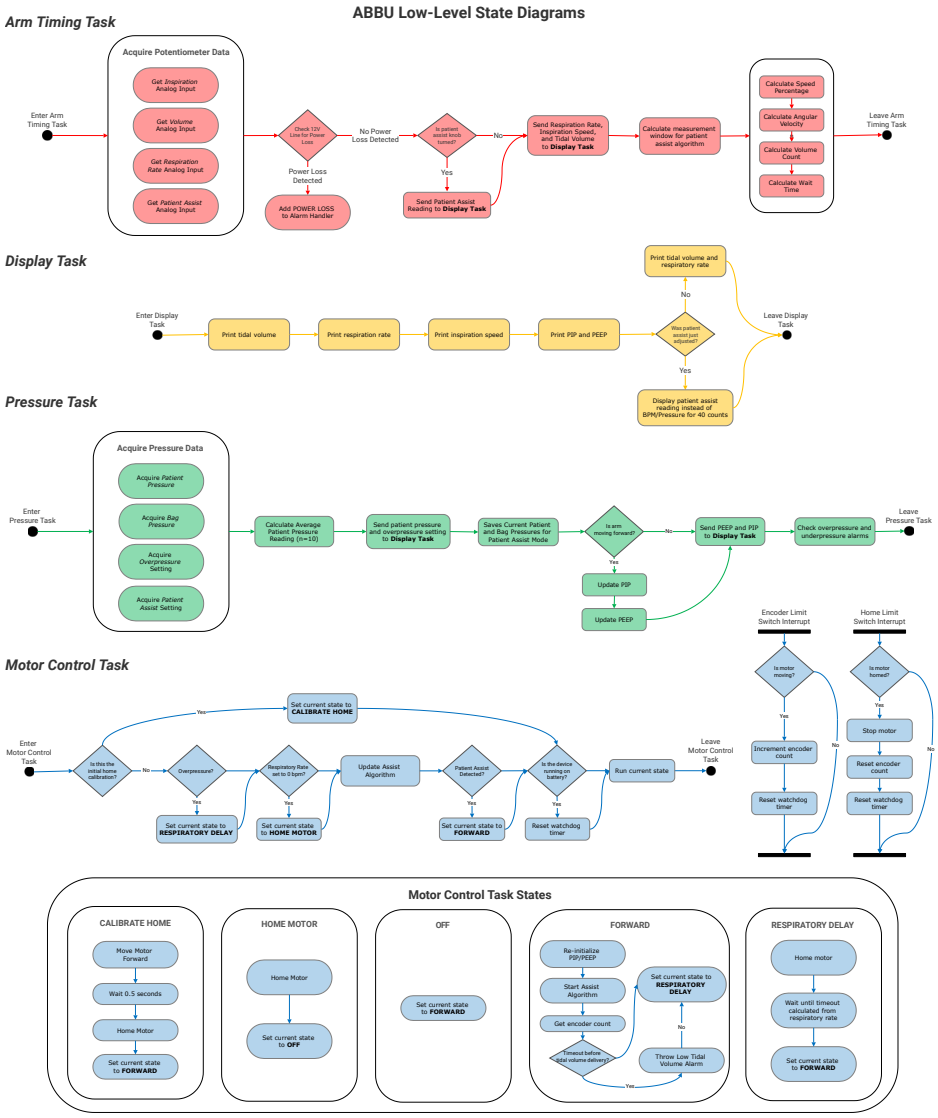


Figure 4.2: Arm, Display, Pressure, and Motor control task state diagrams. Credit to Ronit Kar for laying this out.

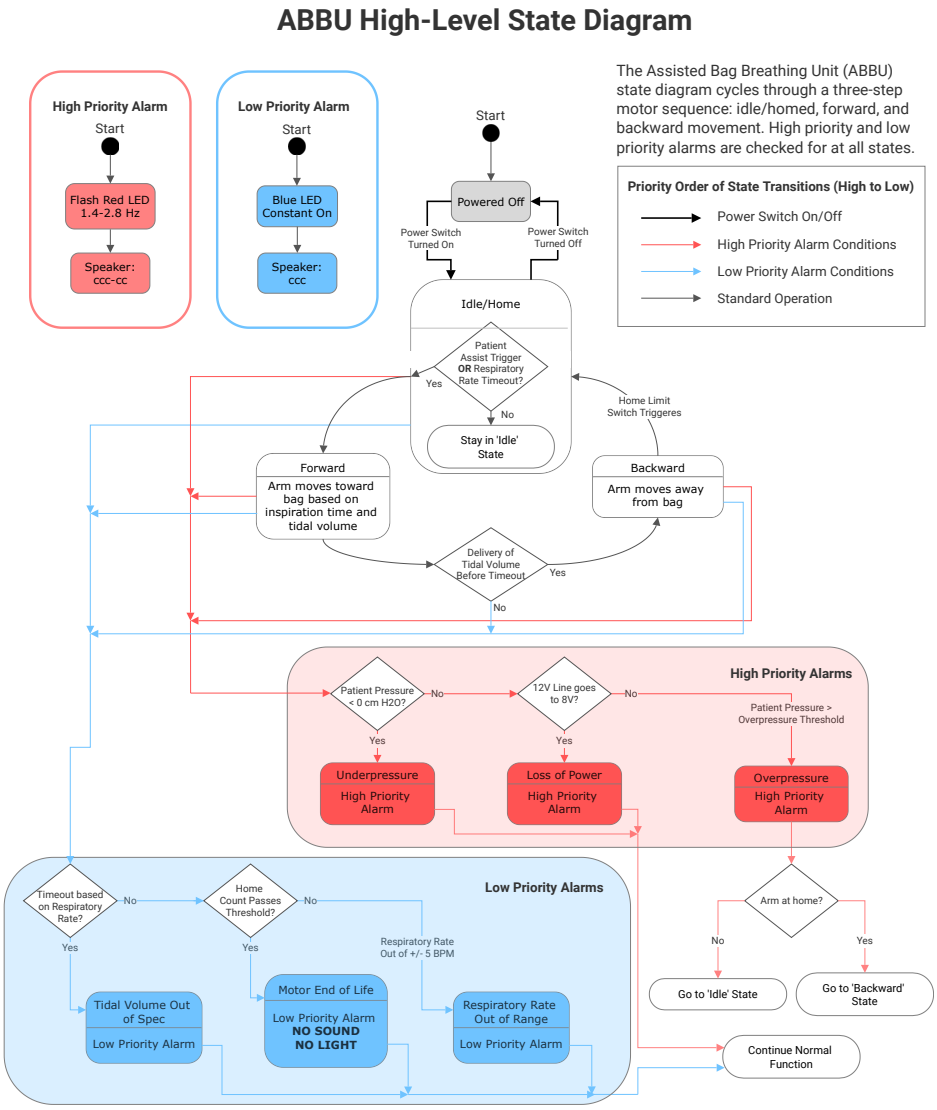


Figure 4.3: Alarm task and some of the higher level operations. Credit to Ronit Kar for laying this out.

Chapter 5

ABBU Validation

If the above reads as an engineering requirement, it is, but does it all work? Exhaustive testing was performed in the laboratory and animals labs to ensure that setting a respiration rate physically translated to the correct number of bag strikes a minute.

I would like to thank Dr. Nitesh Katta, Dr. Aleksandra Gruslova, Scott Jenney, Dr. Jonathan Valvano, and Giles Cabe for their daily and tireless efforts to collect the data that is summarised in this section. Their efforts also formed the basis for the FDA submission and rebuttals. Further reading on the animal experiments and patient assist details can be found in work published by Dr. Aleksandra Gruslova [2].

Typical data that was collected can be seen in Figure 5.1 which shows a round of experiments using the ABBU with a breathing circuit on the Michigan Lung and Biopac. Experiment variables are in columns under "Operating Setpoint", with the measured results in the columns under "Data Measured". This data has been submitted to the FDA to demonstrate that the user inputs from the front panel correspond to the correct device outputs. The testing equipment and what was measured is discussed below.

Evaluation of Targeted Tidal Volume, Pressure, and Flow Rate of ABBU													
	Operating Setpoint						Data Measured						
Excel Tab ID	LUNG COMPLIANCE (L/cm H2O)	MICHIGAN LUNG resistance (cm H2O / L/sec)	TIDAL VOLUME (mL)	RESPIRATORY RATE (BPM)	MANUAL PEEP VALVE (cm H2O)	INSPIRATION TIME (s)	PEAK PRES. (cm H2O) (PIP)	MIN PRES. (cm H2O) (PEEP)	AVERAGE TIDAL VOLUME (mL)	TIDAL VOLUME (L) STDev	RESPIRATORY RATE (BPM)	PERIODS CAPTURED (data points use in avg)	Over pressure (OP) Alarm limit 70cm
400mL	0.01	5	400	20	5	1	49	9	367	37	20	20	no
	0.02	5	400	20	5	1	38	9	415	46	19	20	no
	0.04	5	400	20	5	1	33	10	439	46	19	19	no
600mL	0.01	5	600	20	5	1	65	9	481	42	19	20	Intermittent
	0.02	5	600	20	5	1	47	9	608	25	20	20	no
	0.04	5	600	20	5	1	38	11	647	34	19	19	no
800mL	0.01	5	800	20	5	1	70	3	510	10	19	20	OP Alarm
	0.02	5	800	20	5	1	50	4	752	25	19	20	no
	0.04	5	800	20	5	1	39	5	863	74	20	19	no
200ml 50Rp	0.01	50	200	20	5	1	44	8	212	12	20	20	no
	0.02	50	200	20	5	1	42	8	211	30	20	20	no
	0.04	50	200	20	5	1	40	7	201	14	20	19	no
400mL 50Rp	0.01	50	400	20	5	1	55	7	358	42	20	20	no
	0.02	50	400	20	5	1	53	7	364	36	20	20	no
	0.04	50	400	20	5	1	52	6	375	49	20	19	no
600mL 50 Rp	0.01	50	600	20	5	1	60	3	542	58	20	20	OP Alarm
	0.02	50	600	20	5	1	69	2	628	56	20	20	Intermittent
	0.04	50	600	20	5	1	50	4	561	61	20	19	no
800mL 50 Rp	0.01	50	800	20	5	5	NA	NA	NA	NA	NA	3	OP Alarm
	0.02	50	800	20	5	1	65	6	754	41	20	20	Intermittent
	0.04	50	800	20	5	1	63	6	825	41	20	19	no

Figure 5.1: Real world ABBU data sent to the FDA

5.1 Testing Equipment

Besides standard oscilloscopes, multi-meters, and debuggers, specialized equipment was needed to measure the transduced physical outputs of the ABBU. The equipment also needed to be calibrated so the ABBU team and the FDA could be assured that measurements are traceable and repeatable.

5.1.1 Michigan Lung

The Michigan Lung is a teaching and testing tool designed to mimic the human lungs. It has tools to measure respiration rates, tidal volumes, inspiration times, and lung pressure. The simulator can also be configured with different lung resistances and compliances, critical for testing a ventilator that could be used on a range of patients.

In short, lung resistance is a change in pressure divided by the flow rate, and compliance is volume divided by a change in pressure. Patients that have COVID would have a high resistance and low compliance, i.e it is hard to get air into the lungs and the lungs don't inflate much.

5.1.2 Biopac

Though a powerful tool, the Michigan Lung lacks the ability to collect flow information. To validate that flow rates and pressure at the input side of the breathing circuit were safe, a Biopac was configured with a calibrated flow and pressure meter. The Biopac is a data collection tool designed to collect biological measurements from multiple sensors and can be configured as needed.

5.2 PicoScope

For the electrical measurements, an oscilloscope was needed to ensure that the signal to drive the piezo speaker was the correct frequency and the peizo produced a sufficiently loud (and correct) tone. Dr. Valvano used a PicoScope 2104 to acquire electrical signals and when combined with microphone, the auditory signal could be transduced and measured using the PicoScope.

5.3 Breaths Per Minute

To measure the Breaths Per Minute, the ABBU was connected to a breathing circuit, the Michigan Lung, and the Biopac. Biopac data was collected for several minutes and verified against the set value to validate that number of bag strikes per minute matched the request number of breaths per minute.

5.4 Tidal Volume

Tidal volume is the amount of air inhaled during a breath, and is ideally the volume of air delivered to a patient per breath. This was measured using the Biopac in conjunction with the Michigan Lung. The Michigan lung was typically set to 200ml, 400ml, 600ml, or 800ml when submitting data to the FDA (Figure 5.1).

5.5 Patient Assist

Delving into the patient assist is beyond the scope of this thesis, as this work was done by mostly by Dr. Valvano and Dr. Derdak. It was, however, extensively tested in a porcine animal model and written up by Dr. Gruslova [2] to show that both the front panel value matched the correct physiological pressure drops and that the patient assist did, indeed, work.

5.6 Inspiration Time

Inspiration time is the duration in which the tidal volume is delivered. This can be measured using the Biopac by taking the difference in time between lowest pressure before the arm strike and the maximum pressure after the arm strike.

5.7 Over Pressure

Over pressure was tested by increasing the reducing the compliance of the Michigan Lung and setting ABBU to deliver a high tidal volume. This was usually performed as a pass fail test.

5.8 Pressure Transducer Acquisition Rate

ABBU will be used in safety critical situations, where the patient's life is at stake and pressure acquisition timing is critical. The task switching on the ABBU is handled by the Arduino software with the pressure being acquired by a real-time task at a rate of 100 Hz. To confirm that the pressure transducer task is being called every 10ms, data was taken on a slightly modified ABBU unit that emits a digital high when pressure transducer acquisition was happening, and low when no transducer acquisition is happening. Data was acquired for 10 seconds during typical operation without a breathing circuit to ensure that alarms were active which represents the highest workload that the processor would be under.

The acquired data was processed to create an array of differences in time (delta time) between pressure transducer acquisition trigger events. This data was placed into bins that were separated by 1.5ms increments and plotted. This data can be seen in Figure 5.2. Of the data collected, the median delta time was 10ms and the mean and standard deviation of the delta times is 12ms and 8ms, respectively. For the most part, the task timing events for the pressure transducer occurred at the desired rate of 10ms, but there are enough events occurring at a 40ms delta to investigate why this is happening.

Of the n=784 timing events captured, 707 events fell into the correct timing domain, where roughly 10% (77 events) fell outside. Furthermore, the events that occurred outside of the 10ms range appeared to occur periodically and not "in a row", which can be seen in Figure 5.3. This graph shows the delta time events (n=784) in the sequence they were acquired and seems to show that there is a task running periodically that is finishing late and causing a delay in the pressure acquisition task starting but the system rapidly recovers the default timing scheme. Despite this error in real time task switching, the ABBU is able to maintain the critical care needs set by the operator to the patient in both the laboratory and real world animal model testing.

To better map timing, each task could have a digital event occur at the start and end of the task, and all tasks acquired. Timing analysis could determine where certain tasks are hogging the processor and try and adjust timing. Some low hanging fruits to improve task timing performance would be a hardware PWM signal (instead of hardware interrupts) and converting ABBU to an FPGA project

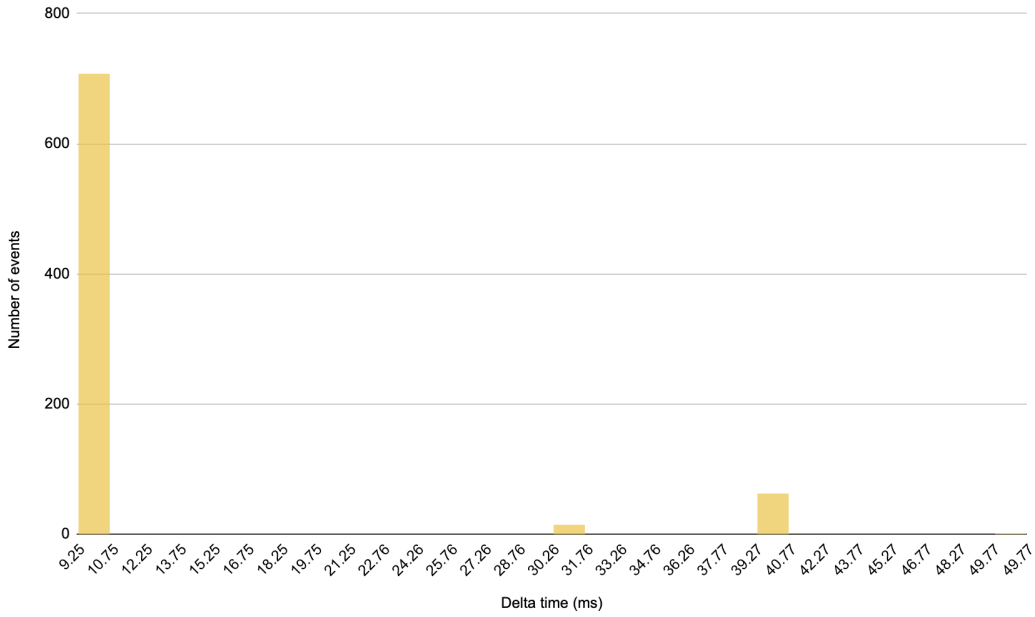


Figure 5.2: Histogram of difference in time that occurs between pressure transducer acquisitions over a 10 second period under heavy processor load.

which would completely eliminate task switching all together; a direction that would have made the most sense if time hadn't been an issue.

5.9 Alarms

Alarms were configured to meet IEC 60601-1-8 for tone and ISO 3744 to ensure sufficient loudness There were three types of alarms that needed to be tested:

- High Priority Alarm - Three C5 notes, a 200ms pause, and two more high C notes, and a 1 second pause
- Low Priority Alarm - Three C notes and a 1 second pause
- Power Loss Alarm - One C4 note, two C5 notes, a 200ms pause, a C4 followed by a C5, and a 1 second pause

Figure 5.4 shows an acquisition from the Pico Scope that demonstrates that C5 is the correct frequency with a signal to noise ratio of 30dB. C4 was validated

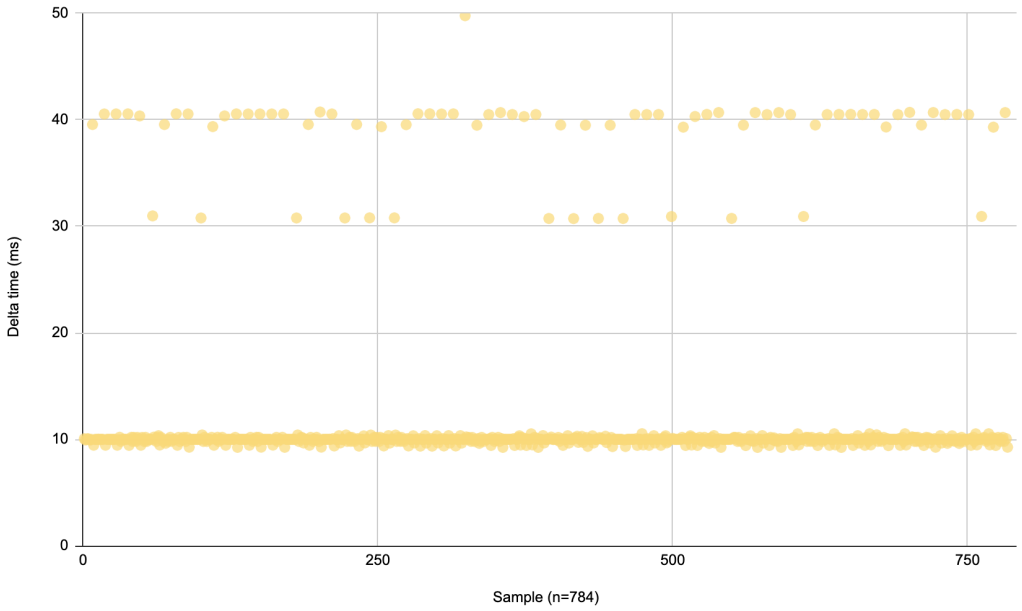


Figure 5.3: Delta time between pressure acquisition sequentially captured.

using the same technique.

5.10 Loss of Power Battery based Alarm duration

The loss of power battery test was to validate that the alarm was active for the stated duration of 10 minutes. This was accomplished by unplugging the unit and ensuring the LEDs and alarms were active while measuring the time with a stop watch.

Further validation was performed using the PicoScope to measure the voltage on input power to the Arduino. If this voltage fell below 10VDC, then the unit was determined to be running on battery.

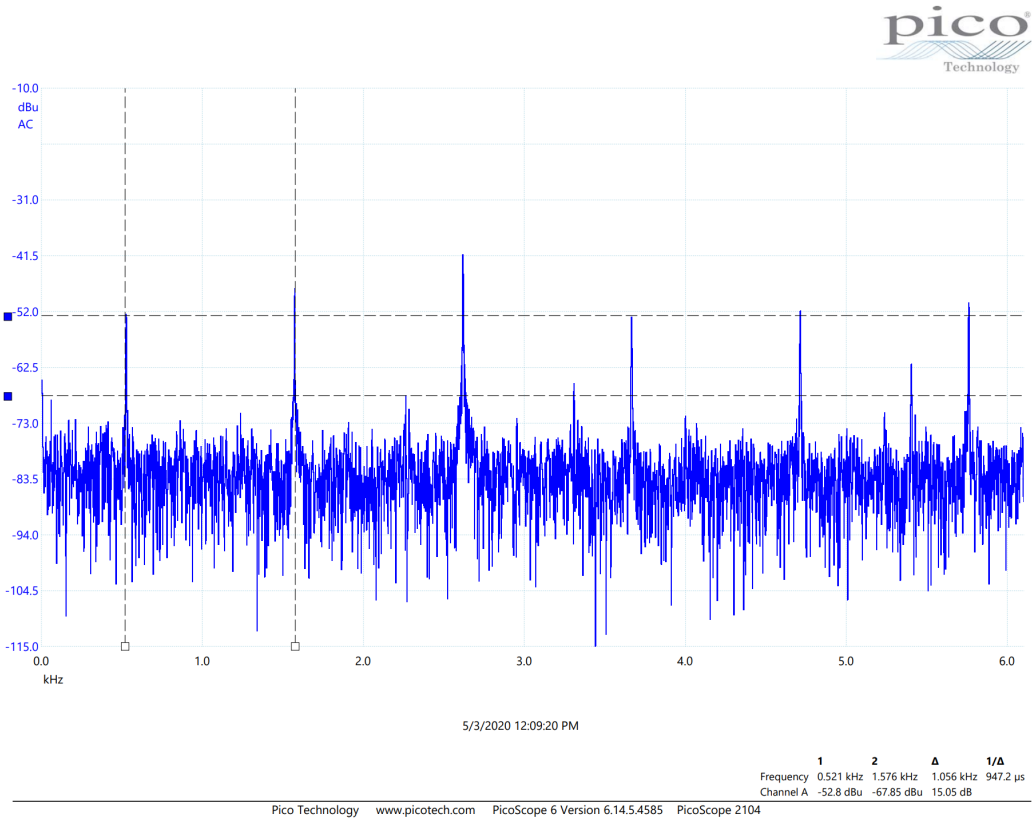


Figure 5.4: Spectrum acquired by the Pico Scope to show correct C5 frequency at 523.25Hz.

Appendix A

Lung Power Calculations

Outline of Motor Power Requirement Estimate
March 21, 2020

Outline:

1. Energy/Power into Ambu Bag: Use Scott's measurements for computation of energy/power
2. Power/Energy Loss is 10 ft long 18mm ID tube
3. Power/Energy Loss in Pulmonary Resistance
4. Energy/Power for Lung Compliance
5. Consider Peak and Average Power for motor

Energy/Power/Pressure Conversions:

1 cmH_20 = 98.06 Pascals

1 cmH_2O * ml = 0.098 mJ

1 cmH_2O * ml/s = 0.098 mW

---

1. Energy/Power into Ambu Bag:

Change in pressure is 3 kg over 1" diameter this converts to 5.808 Pascals of pressure. Compliance estimate of Ambu Bag is delta_V/delta_P = 800ml/5.808 Pa = 137.74 ml/Pa or 1.38 10^{-4} m^3/Pa

Energy to Eject 800ml from Ambu Bag: E(Ambu Bag) = 0.5 * V_2^2/C = 2,323.217 ml Pa = 2.31 mJ

Over 0.5 seconds this is a power of 4.646 mW.

---

2. Power Loss is 10ft long Tube: Resistance of the tube is $8\mu L/(\pi R^4)$; Parameters:

Dynamic Viscosity of Air: 1.825 10^{-5} kg/(m s)

Length: 10' is 3.048 meters

π R^4: R=9mm; π $R^4 = 2.0612\ 10^{-8}$ m^4

Resistance: 8 (1.825 10^{-5}) 3.048 /(2.0612 10^{-8}) = 2.159 10^4 [kg/(s m^4)] or (Pa s/m^3)

Resistance in Pulmonary Units: 2.159 10^4 (Pa s/m^2) (1 cmH_20/98.06 Pascals) (m/100 cm)^2 = 0.022 (cmH_2O s/cm)

Instantaneous Power Loss: $P = Q^2 R$ = 0.0016^2 (m^6/s^2) 2.159 10^4 (Pa s/m^3) =0.05527 W or 55.27 mW

Instantaneous Energy Loss over 0.5s: 27.64 mJ

---

3. Power/Energy Loss in Pulmonary Resistance

Lung and Airway Resistance: 1.5 cmH_2O/(L/s), converting to MKS

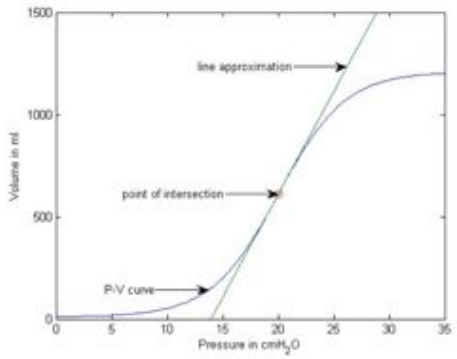
1.5 cmH_2O/(L/s) (98.06 Pascals/cmH_2O) (1 L/s)/(0.001 m^3/s) = 1.471 10^5 (Ps s/m^3)

Instantaneous Power Loss: $P = Q^2 R$ = 0.0016^2 (m^6/s^2) 1.471 10^5 (Pa s/m^3) = 0.3766 W

Instantaneous Energy Loss over 0.5s: 188 mJ

---

4. Energy/Power for Lung Compliance



$$V = a + \left[\frac{b}{1 + e^{-(P-c)/d}}\right]$$

***a*=10ml, *b*=1200ml, *c*=20cmH_2O and *d*=3cmH_2O**

Linear Compliance: delta_V/delta_P = 1500 ml/(14.5 cmH_2O) = 103.45 (ml/ cmH_2O)

Converting to MKS: 103.45 (ml/ cmH_2O) (10^{-6} m^3/ml) (1 cmH_2O/98.06 Pa) = 1.055 10^{-6} m^3/Pa

Energy to Inject 800ml Into Lung: E(Lung) = 0.5 * ($V\_2^2 - V\_1^2$)/C = 0.5 * ($0.001^2 - 0.0002^2$)/(1.055 10^{-6} m^3/Pa) = 0.454 J

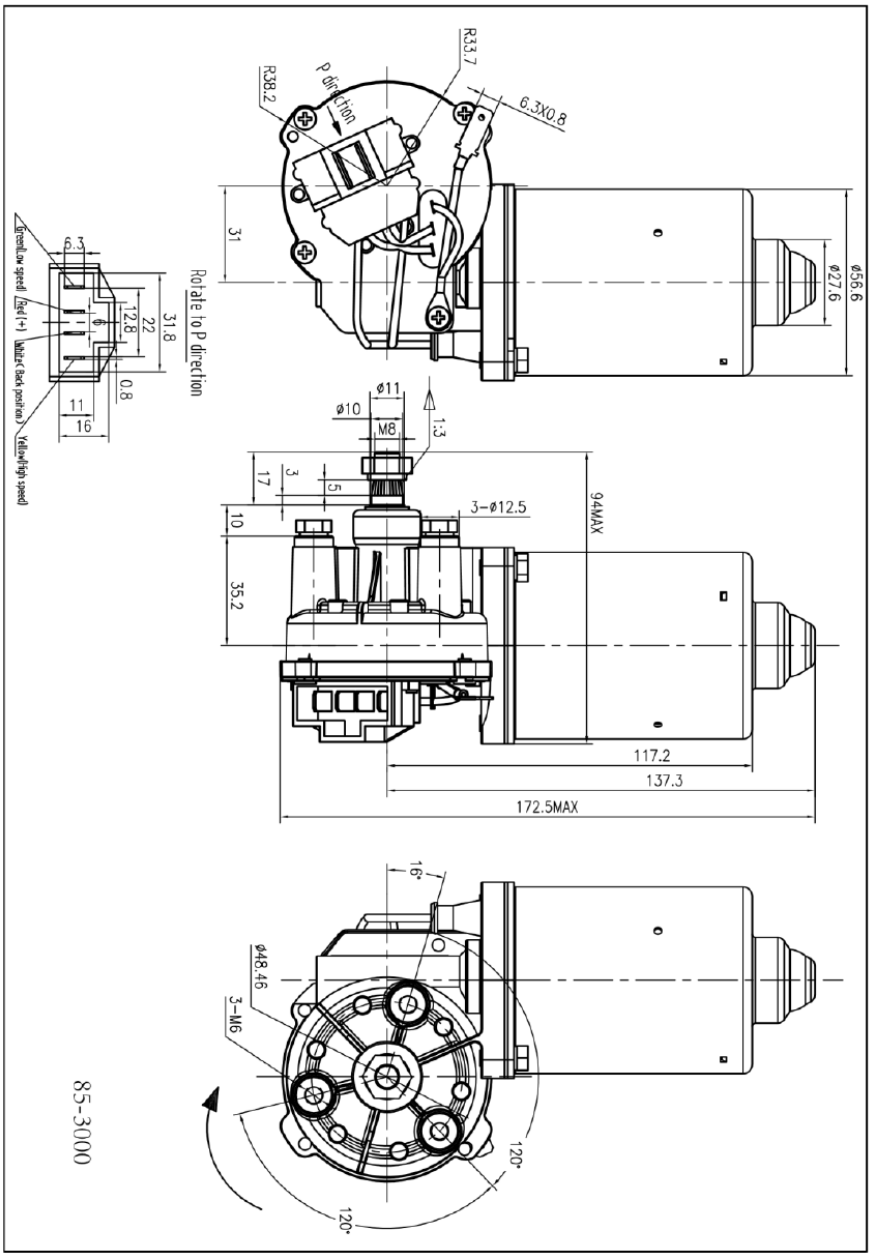
Instantaneous Power: 0.91 W

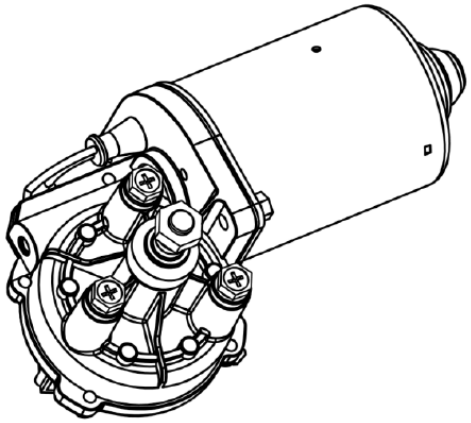
Total Energy: 672mJ

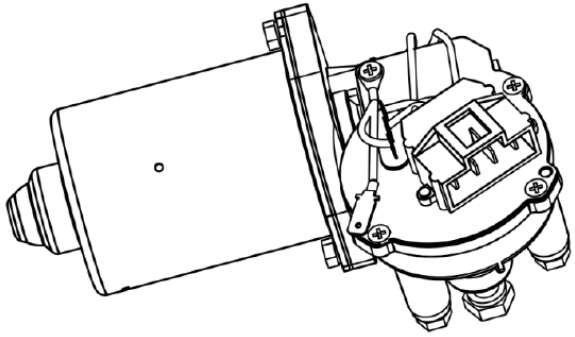
Total Instantaneous Power: 1.344 W

Appendix B

Cardone Motor


R33.7
R38.2
P direction
6.3X0.8
31
ø56.6
ø27.6
6.3
Green(low speed)
Red(+)
White(back position)
Yellow(high speed)
12.8
22
31.8
6
0.8
11
16
Rotate to P direction
ø11
ø10
M8
1:3
3
17
5
3-ø12.5
94MAX
10
35.2
117.2
137.3
172.5MAX
16°
ø48.46
3-M6
120°
120°
85-3000

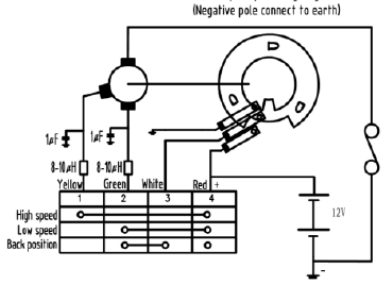




Technical requirements:

1.Testing voltage:DC 13.5±0.2V,CW.	
2.Power(W)	30
3.Stall torque(N.m)	≥18
4.Stall current(A)	≤25
5.No load parameters:	
Low speed(r/min)	50±7
Current(A)	≤2.0
High speed(r/min)	70±7
Current(A)	≤3.0
6.On load Parameters:	
Low speed(r/min)	≥30
Current(A)	≤5.5
High speed(r/min)	≥45
Current(A)	≤6.5

Motor principle wiring diagram.
(Negative pole connect to earth)



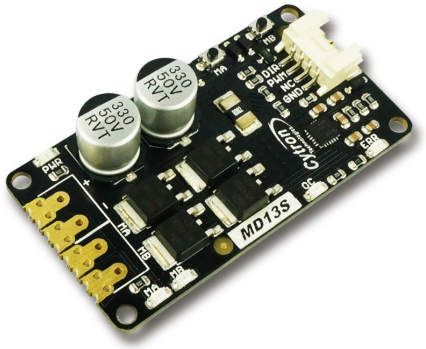
Current/Thermal protect switch
When current is 15A, the switch break time is less than 30s, recover time is less than 10s

85-3000

Appendix C

Cytron MD13S

MD13S
13Amp DC Motor Driver



User's Manual

V1.1

June 2018

INDEX

1. INTRODUCTION/OVERVIEW

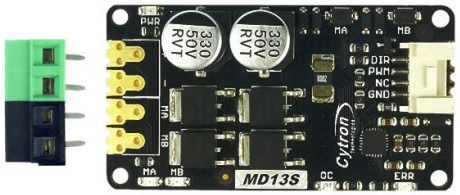
MD13S is designed to drive high current brushed DC motor up to 13A continuously. It offers several enhancements such as support for both locked-antiphase and sign-magnitude PWM signal because it uses full solid state components which is able to provide faster response time and eliminate the wear and tear of the mechanical relay.

The MD13S has been designed with the capabilities and features of:

- Bi-directional control for one brushed DC motor.
- Support motor voltage ranges from **6V to 30V**.
- Maximum current up to **13A continuous** (without heatsink at 25°C) and 30A peak (10 second).
- Current limiting at **30A**.
- 3.3V and 5V logic level input.
- GROVE compatible connector.
- Solid state components provide faster response time and eliminate the wear and tear of mechanical relay.
- Fully NMOS H-Bridge for better efficiency and no heat sink is required.
- Speed control PWM frequency up to 20KHz (Actual output frequency is same as input frequency).
- Support both locked-antiphase and sign-magnitude PWM operation.
- Support TTL PWM from microcontroller, **not PWM from RC receiver**.
- SMD Compatible
- **Dimension:**61mm x 33mm

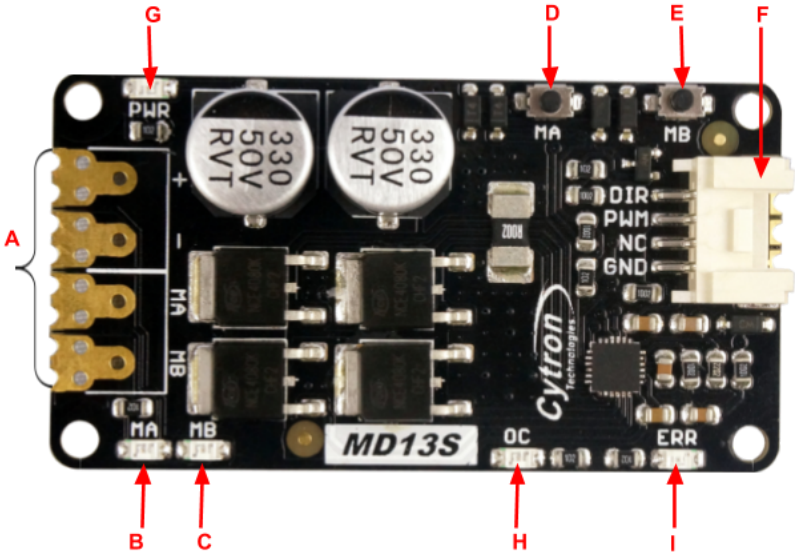
2. PACKING LIST

Please check the parts and components according to the packing list. If there are any parts missing, please contact us at sales@cytron.com.my immediately.



1. 1 x MD13S 13A DC Motor Driver.
2. 2 x Terminal socket, Black for power and Green for Motor.
3. Grove connector with cable.
4. User's manual can be downloaded from here
5. If you like to get MD13S, please get it from our online store here: https://www.cytron.io/p-md13s

3. BOARD LAYOUT AND SPECIFICATION



Label	Function
A	Terminal Block
B	MA LED Indicator
C	MB LED Indicator
D	MA Test Switch
E	MB Test Switch
F	Input pin
G	Power LED Indicator
H	OC LED Indicator
I	ERR LED Indicator
J	SMD Compatible

1. Terminal Block – Connect to motor and power source.

Pin No.	Pin Name	Description
1	POWER +	Positive Supply (6V to 30V)
2	POWER -	Negative Supply
3	Motor Output A	Connect to motor terminal A
4	Motor Output B	Connect to motor terminal B

2. MA LED Indicator – Turns on when the output A is high and output B is low. Indicates the current flows from output A to B.

3. MB LED Indicator – Turns on when the output A is low and output B is high. Indicates the current flows from output B to A.

4. MA Test Switch – When this button is pressed, current flows from output A to B and motor will turn CW (or CCW depending on the connection).

5. MB Test Switch – When this button is pressed, current flows from output B to A and motor will turn CCW (or CW depending on the connection).

6. Input

Pin No.	Pin Name	Description
1	GND	Logic ground.
2	**PWM	PWM input for speed control
3	DIR	Direction control.

**Note that it is not for RC PWM operation

The truth table for the control logic is as follow:

Pin 2 (PWM)	Pin 3 (DIR)	Output A	Output B
Low	X (Don't care)	Low	Low
High	Low	High	Low
High	High	Low	High

7. Power LED Indicator – Power LED. Should be on when the board is powered on.
8. OC (Over Current)LED Indicator, Output current is over 30A limit.
9. ERR LED Indicator - Error LED Indicator, it will illuminate when fault detected in on board MOSFET driver.
10. SMD compatible

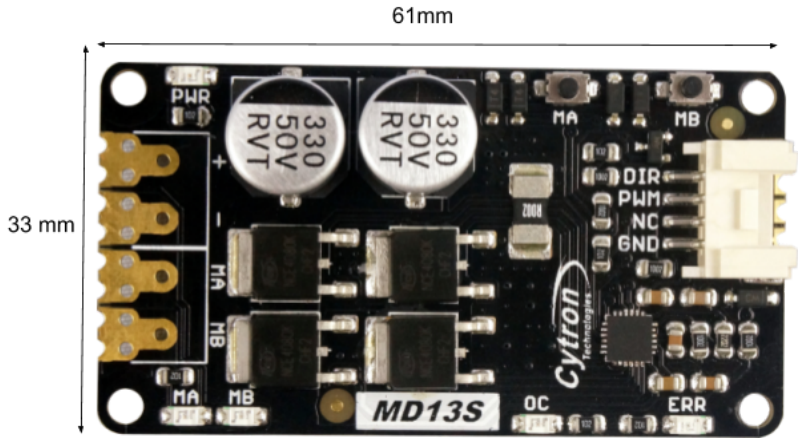
4. PRODUCT SPECIFICATION AND LIMITATIONS

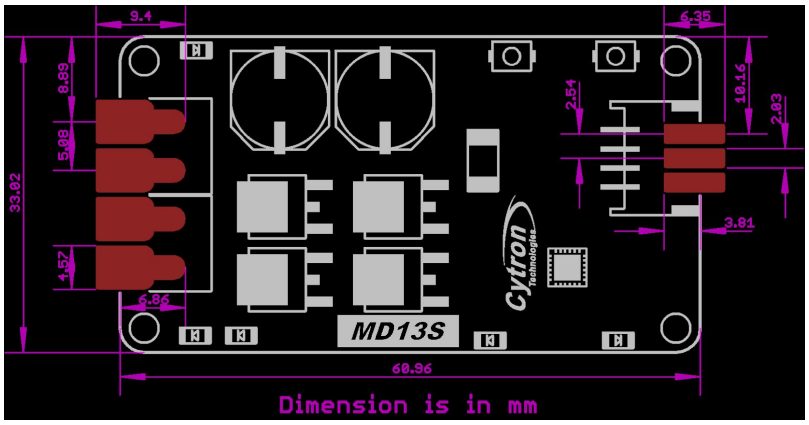
Absolute Maximum Rating

No.	Parameters	Min	Typical	Max	Unit
1	Power Input Voltage	6	-	30	V
2	I_{MAX} (Maximum Continuous Motor Current)	-	-	13	A
3	I_{PEAK} – (Peak Motor Current) *	-	-	30	A
4	V_{IOH} (Logic Input – High Level)	3	-	5.5	V
5	V_{IOL} (Logic Input – Low Level)	0	0	0.5	V
6	Maximum PWM Frequency **	-	-	20	KHz

**** Must not exceed 10 seconds.***
***** Actual output frequency is same as input frequency.***
****** Tested in room temperature.***

5. DIMENSION





Footprint Dimension

*Eagle CAD Library

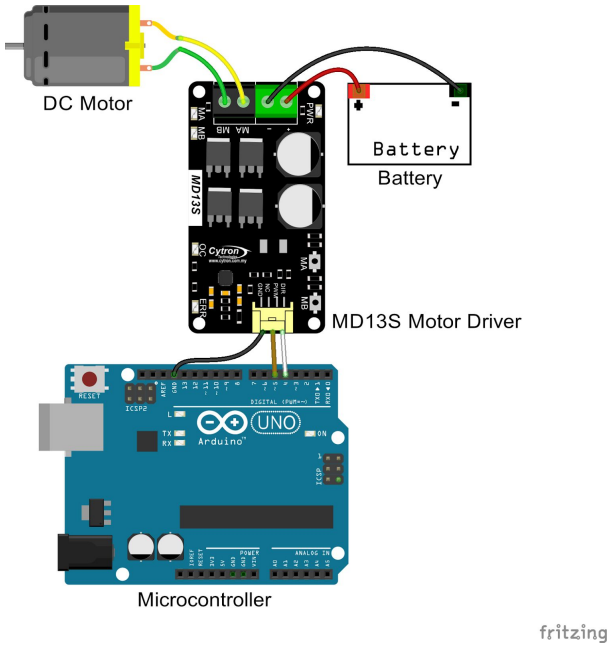
6. GETTING STARTED

MD13S is compatible with 2 types of PWM operation, which are:

1. Sign-Magnitude PWM – For sign-magnitude PWM operation, 2 control signals are used to control the speed and direction of the motor. PWM is feed to the PWM pin to control the speed while DIR pin is used to control the direction of the motor.

2. Locked-Antiphase PWM – For locked-antiphase PWM operation, only 1 control signal is needed to control the speed and direction of the motor. PWM pin is connected to logic high while the DIR pin is being feed with the PWM signal. When the PWM signal has 50% duty cycle, the motor stops running. If the PWM has less than 50% duty cycle, the motor will turn CW (or CCW depending on the connection). If the PWM signal has more than 50% duty cycle, motor will turn CCW (or CW depending on the connection).

Sample connection diagram is as follow:



7. WARRANTY

- Product warranty is valid for 12 months.
- Warranty only applies to manufacturing defect.
- Damaged caused by misuse is not covered under warranty
- Warranty does not cover freight cost for both ways.

Prepared by:
Cytron Technologies Sdn. Bhd.
No. 1, Lorong Industri Impian 1,
Taman Industri Impian,
14000 Bukit Mertajam,
Penang, Malaysia.
Google Maps

Tel: *+604-548 0668*
Fax: *+604-548 0669*

URL: www.cytron.io
Email: support@cytron.io
sales@cytron.io

Appendix D

Inventus MWA220

MWA220 Series

220 W Medical Desktop Power Supply

- High Efficiency
- High Power Density 5.9W/in3
- 5-Year Limited Warranty
- LED Status Indicator
- IPX1 Rated
- Hold-up Time > 25ms at full load
- Medical Approval - EN60601-1 Class I 3rd Edition
- Level V; EISA, EuP Directive Compliant
- CEC Compliant

Elpac Part Number	Output Voltage	Output Current	Peak Current	Total Regulation	Typical Efficiency
MWA220012A-13A	12.0V	18.3A	19.0A	±5%	89%
MWA220015A-13A	15.0V	14.6A	15.2A	±5%	89%
MWA220018A-13A	18.0V	12.2A	12.7A	±5%	90%
MWA220024A-12A	24.0V	9.2A	9.5A	±5%	90%
MWA220028A-12A	28.0V	7.8A	8.0A	±5%	90%
MWA220032A-12A	32.0V	6.8A	7.0A	±5%	91%
MWA220048A-11A	48.0V	4.6A	4.7A	±5%	91%

Input	
Input Voltage	85 - 264VAC; 100 – 240VAC Nominal
Input Frequency	47 - 63Hz
Input Current	<3A rms
Inrush Current	<37A at 230VAC cold start
Power Factor	>0.97
Zero Load Power Consumption	<0.5 Watt
Earth Leakage Current (Typical)	<200µA @ 132VAC @ 60Hz
	<300µA @ 264VAC @ 60Hz
Patient Leakage Current	<100µA @ 132VAC @ 60Hz
	<100µA @ 264VAC @ 60Hz

Output	
Output Voltage	See Table
Total Regulation	+/-5%
Minimum Load	No minimum load required
Start-Up Delay	<1.5s
Hold-Up Time	>25ms at any input voltage
Ripple & Noise	<1% pk-pk **
Over Voltage Protection	110-135%
Over Temperature Protection	Active - Recoverable; plus Passive - Non Recoverable
Over Current Protetion	105 - 110%
Short Circuit Protection	shutdown, auto-restart (hiccup mode)

General	
Efficiency	Avg Efficiency 90.5% @ 115VAC; 92.5% @ 230VAC
MTBF	min. 200,000 hours demonstrated
Size	8.2" (208mm) x 2.9 (73mm) x1.6 (39mm)
Weight	2.1 lbs (0.95 kg)
Power Density	5.9W/in³

Environmental	
Operating Temperature	0 – 60°C (Full load to 40°C, derate linearly to 50% load at 60°C)
Storage Temperature	-40°C to +85°C
Relative Humidity	15-95%, non-condensing
Cooling	Natural Convection
Vibration	All units production tested to 19.6m/s2

EMC & Safety	
Emissions	EN55011 and FCC Part 15, Class B Conducted and Radiated
Immunity	EN61000-3-2,-3; EN61000-4-2, -3, -4, -5, -6, -8, -11
Certified by TUV to the following: 	cTUVus
	UL 60601-1
	CAN/CSA-22.2 No.601.1-M90
	IEC60601-1, 2nd and 3rd edition
	CE marked to LVD

Input Configuration	
Standard Input Cable	Not Provided
Connection on Power Supply Body	IEC 320 C14 Receptacle

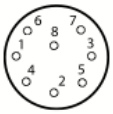
Output Configuration (12V - 18V)	
Standard Output Cable	4 ft.
Cord Size	4x16awg
Connector (PSU side)	Molex 6 pin P/N 39-01-2065
Mating Connector	Molex 39-01-2061 or 26-01-3116

Output Configuration (24V - 32V)	
Standard Output Cable	6 ft.
Cord Size	4x18awg
Connector (PSU side)	Switchcraft DIN-8, P/N 15BL8MX (male pins)
Mating Connector	Switchcraft 62GB8FX (8 pin) or equivalent

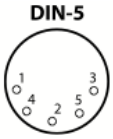
Output Configuration (48V)	
Standard Output Cable	6 ft.
Cord Size	2x16awg
Connector (PSU side)	Switchcraft DIN-5, P/N 05GM5MX (male pins)
Mating Connector	Switchcraft 57GB5FX (5 pin) or equivalent

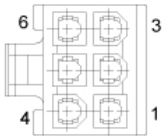
Output Pin Assignments

DIN-8

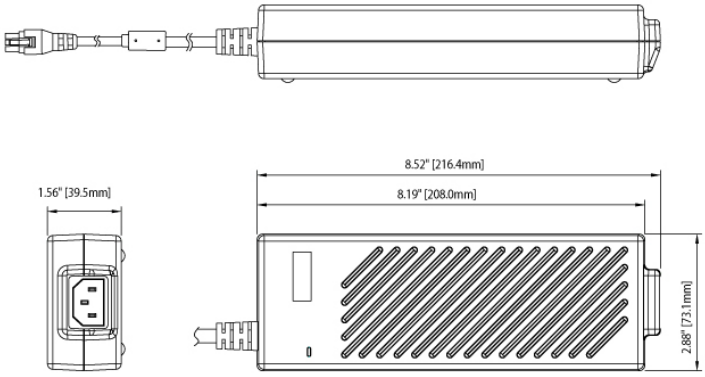


Pin 1	+V1
Pin 2	+V1
Pin 3	Return
Pin 4	+V1
Pin 5	Return
Pin 6	+V1
Pin 7	Return
Pin 8	Return

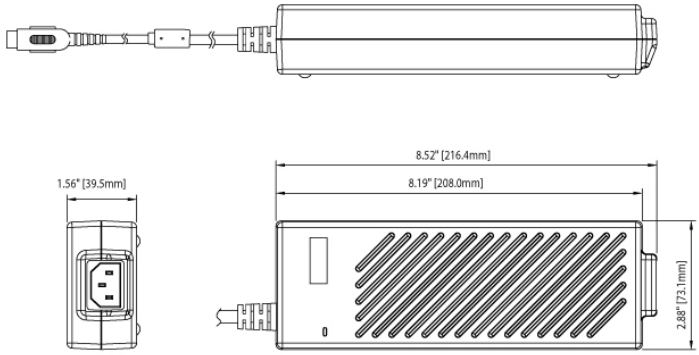
Output Pin Assignments	
DIN-5 	
Pin 1	Return
Pin 2	Return
Pin 3	+V1
Pin 4	Return
Pin 5	+V1

Output Pin Assignments (12V-18V)	(viewed from the open/user end)
	
Pin 1	Return
Pin 2	Return
Pin 3	Shield
Pin 4	+V1
Pin 5	+V1
Pin 6	Not Used

12V Model



24V-48V Models



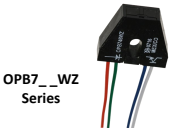
Appendix E

Reflective Sensor OPB745

Reflective Object Sensor

OPB708, OPB709

OPB740 Series, OPB740WZ Series



Features:

- Focused for maximum sensitivity
- Phototransistor or photodarlington output
- Crosstalk does not exceed specified ICEO
- 24" (610 mm) wire length
- 26 AWG wire size

Description:

Each reflective object sensor in the **OPB708**, **OPB709**, **OPB740** through **OPB746** and **OPB740WZ** through **OPB746WZ** series consists of an infrared emitting diode and a NPN silicon phototransistor or a photodarlington. The **OPB747WZ** and **OPB748WZ** consist of a Red visible LED and a low light level rejection (R_{BE}) NPN silicon phototransistor. The Red LED allows better contrast ratio when detecting Black marks on a White surface. All these devices are mounted side-by-side on converging optical axes in a black plastic housing focusing on a small area and depth of field.

OPB7 _ _ WZ series are wired (UL approved wire) devices that offer various lens options, including no windows, blue polysulfone windows for dust protection or opaque aperture windows with offset openings for improved target resolution.

On each sensor included in this data sheet, the photosensor responds to radiation only when a reflective object passes within its field of view.

Custom IC(ON) current binning, special wire lengths and connectorization is available through your OPTEK rep.

Applications:

- Non-contact reflective object sensor
- Assembly line automation
- Machine automation
- Machine safety
- End of travel sensor
- Door sensor
- Thermal Paper Mark

CONTAINS POLYSULFONE

To avoid stress cracking, we suggest using ND Industries' **Vibra-Tite** for thread-locking. **Vibra-Tite** evaporates fast without causing structural failure in OPTEK's molded plastics.
Applies to: OPB460, OPB470, OPB480, OPB490.

RoHS

Part Number	LED Peak Wavelength	Sensor	Reflection Distance Inch (mm)	Lead Length/ Wire Type
OPB708	935 nm	Transistor	Min=0.08" [2.04mm] Typ=0.15" [3.81mm] Max=0.30" [7.62mm]	0.150" Minimum
OPB709		Darlington		
OPB740	890 nm	Transistor		
OPB741				
OPB742				
OPB743				
OPB744				
OPB745		Darlington		
OPB740WZ		Transistor		24" / 26 AWG Wire
OPB741WZ				
OPB742WZ				
OPB743WZ				
OPB744WZ				
OPB745WZ		Darlington		
OPB746WZ	935 nm	R_{BE} Transistor		
OPB747WZ	645nm			
OPB748WZ		Transistor		

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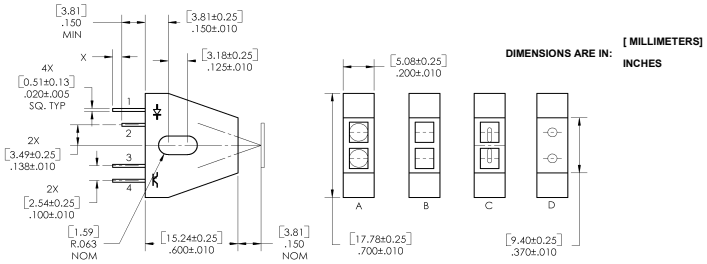
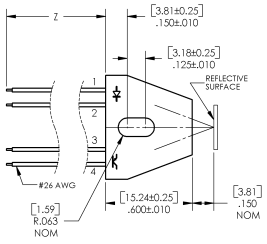
www.optekinc.com | www.ttelectronics.com

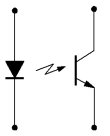
OPB708, OPB709, OPB740, OPB741, OPB742, OPB743, OPB744, OPB745



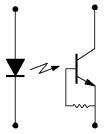
OPB740WZ, OPB741WZ, OPB742WZ, OPB743WZ, OPB744WZ, OPB745WZ, OPB746WZ, OPB747WZ, OPB748WZ



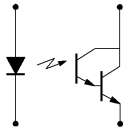
OPB708
OPB740 thru **OPB744**
OPB740WZ thru **OPB744WZ**



OPB746WZ, OPB747WZ, OPB748WZ



OPB709, OPB745, OPB745WZ



Color-PIN #	LED	Color-PIN #	Transistor
Orange-1	Anode	White-4	Collector
Green-2	Cathode	Blue-3	Emitter

Package Style	
Part Number	**Lens Configuration**
OPB708	D - No windows
OPB709	D - No windows
OPB740	A - No windows
OPB740WZ	A - No windows
OPB741	B - Blue windows
OPB741WZ	B - Blue windows
OPB742	C - Offset windows
OPB742WZ	C - Offset windows
OPB743	A - No windows
OPB743WZ	A - No windows
OPB744	B - Blue windows
OPB744WZ	B - Blue windows
OPB745	C - Offset windows
OPB745WZ	C - Offset windows
OPB746WZ	B - Blue windows
OPB747WZ	C - Offset windows
OPB748WZ	C - Offset windows

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Absolute Maximum Ratings (T_A = 25° C unless otherwise noted)	
Operating and Storage Temperature Range	
OPB708, OP709, OPB740, OPB741, OPB742, OPB743, OPB744, OPB745	-40° C to +85° C
OPB741WZ, OPB742WZ, OPB743WZ, OPB744WZ, OPB745WZ, OPB746WZ, OPB747WZ, OPB748WZ	-40° C to +80° C
Lead Soldering Temperature [1/16 inch (1.6mm) from the case for 5 sec. with soldering iron][1]	260°C
Input Diode (See OP165 (935 nm), OP265 (890 nm) or OVLAS6CB8 (645 nm) for additional information)	
Forward DC Current	40 mA
Reverse DC Voltage	2 V
Power Dissipation[2]	100 mW
Sensor Output (See OP505 (Transistor), OP705 (R_{BE} Transistor) or OP535 (Darlington) for additional Information)	
Collector-Emitter Voltage	
OPB708	30 V
OPB709	15 V
OPB740, OPB741, OPB742, OPB743, OPB744	30 V
OPB740WZ, OPB741WZ, OPB742WZ, OPB743WZ, OPB744WZ OPB748WZ	30 V
OPB745	15 V
OPB745WZ	15 V
OPB746WZ, OPB747WZ	24 V
Emitter-Collector Voltage	
OPB708 through OPB745, OPB748	5.0 V
OPB746 through OPB747	0.4 V
Power Dissipation[2]	100 mW

Notes:
1. RMA flux is recommended. Duration can be extended to 10 seconds maximum when flow soldering.
2. Derate linearly 1.33 mW° C above 25° C.

Electrical Characteristics (T_A = 25° C unless otherwise noted)

SYMBOL	PARAMETER	MIN	TYP	MAX	UNITS	TEST CONDITIONS
645 nm LED (See OVLAS6CB8 for generic information — for reference only)						
V_F	Forward Voltage	-	-	2.6	V	I_F = 20 mA
I_R	Reverse Current	-	-	100	µA	V_R = 2 V
890 nm LED (See OP265 for additional information — for reference only)						
V_F	Forward Voltage	-	-	1.8	V	I_F = 40 mA
I_R	Reverse Current	-	-	100	µA	V_R = 2 V
935 nm LED (See OP165 for additional information — for reference only)						
V_F	Forward Voltage	-	-	1.7	V	I_F = 40 mA
I_R	Reverse Current	-	-	100	µA	V_R = 2 V

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Electrical Characteristics (T_A = 25° C unless otherwise noted)

SYMBOL	PARAMETER	MIN	TYP	MAX	UNITS	TEST CONDITIONS
Output R_{BE} Phototransistor (See OP705 for general information — for reference only)						
$V_{(BR)CEO}$	Collector-Emitter Breakdown Voltage	24	-	-	V	I_C = 100 µA
I_{CEO}	Collector Dark Current	-	-	100	nA	V_{CE} = 10 V, I_F = 0, E_E =0
Output Phototransistor (See OP505 for general information — for reference only)						
$V_{(BR)CEO}$	Collector-Emitter Breakdown Voltage	30	-	-	V	I_C = 100 µA
$V_{(BR)ECO}$	Emitter-Collector Breakdown Voltage	5	-	-	V	I_E = 100 µA
I_{CEO}	Collector Dark Current	-	-	100	nA	V_{CE} = 10 V, I_F = 0, E_E =0
Output Photodarlington (See OP535 for general information — for reference only)						
$V_{(BR)CEO}$	Collector-Emitter Breakdown Voltage	15	-	-	V	I_C = 100 µA
$V_{(BR)ECO}$	Emitter-Collector Breakdown Voltage	5	-	-	V	I_E = 100 µA
I_{CEO}	Collector-Emitter Dark Current OPB709, OPB745, OPB745WZ	-	-	25	µA	V_{CE} = 5 V, I_F = 0, E_E =0
Coupled						
$V_{CE(SAT)}$	Saturation Voltage OPB708 OPB709	- -	- -	0.40 1.10	V	I_F = 40 mA, I_c = 3 µA , d = 0.15”[1][2]
$I_{C(ON)}$[1][2]	On-State Collector Current OPB708 OPB709 OPB740, OPB740WZ OPB741, OPB741W Z OPB742, OPB742WZ OPB743, OPB743WZ OPB744, OPB744WZ OPB745, OPB745WZ OPB746WZ OPB747WZ OPB748WZ	 0.01 1.00 0.05 0.05 0.01 0.20 0.20 5.00 0.50 0.01 0.01	 - - - - - - - - - - -	 3.00 - 2.50 2.50 0.70 2.00 2.00 26.0 2.50 0.70 0.70	mA	V_{CE} = 5 V, I_F = 40mA , d = 0.15” (3.810 mm)
I_{CX}[3]	Crosstalk OPB708, OPB709, OPB740, OPB740WZ OPB741, OPB741WZ OPB742, OPB742WZ OPB743, OPB743WZ OPB744, OPB744WZ OPB745, OPB745WZ OPB746WZ OPB747WZ OPB748WZ	 - - - - - - - - - -	 - - - - - - - - - -	 - 10.0 10.0 1.0 20.0 20.0 25.0 1.0 1.0 1.0	µA	V_{CC} = 5 V, I_F = 40mA

Notes:
1. The distance from the assembly face to the reflective surface is “d”.
2. Reflective surface is Eastman Kodak (Catalog #190 3061) neutral white test card with 90% diffuse reflectance as a reflecting surface.
3. Crosstalk is the photocurrent measured with current to the input diode, no reflective surface and no ambient light (E_E = 0).

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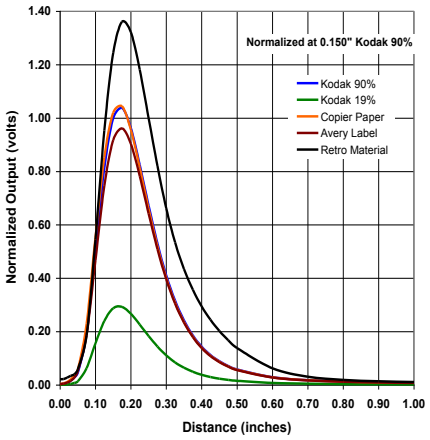
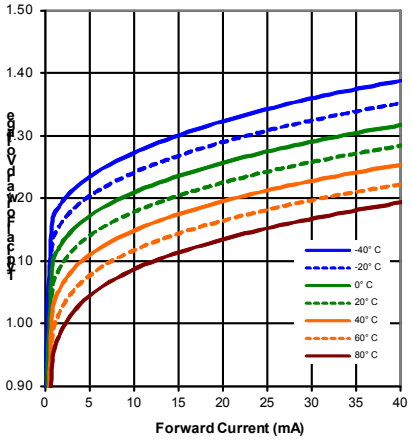
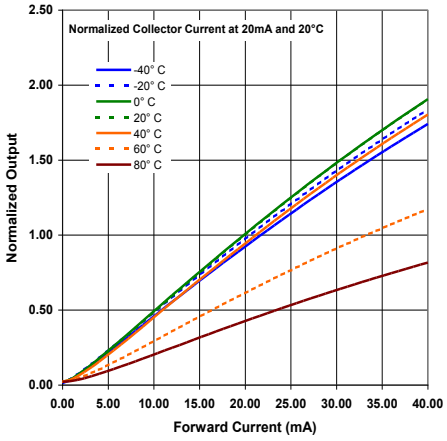
Transistor Output vs Distance



LED Forward Voltage vs Forward Current vs Temperature



Transistor Output vs Forward Current vs Temperature



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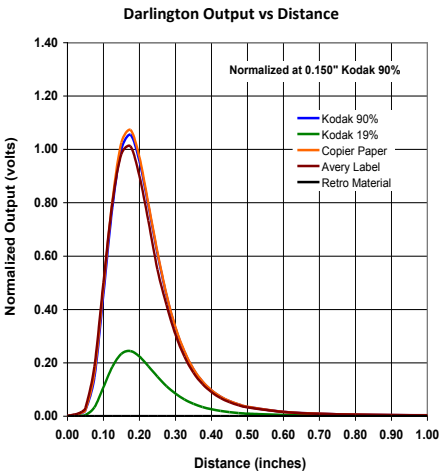
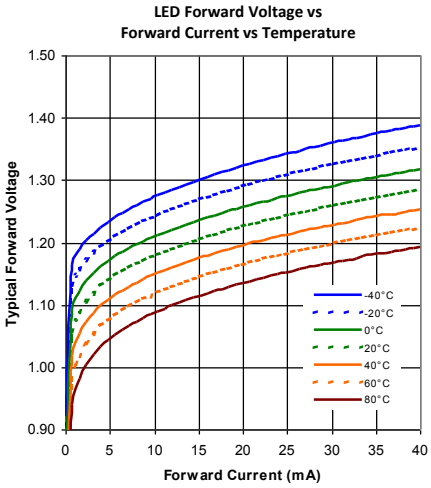
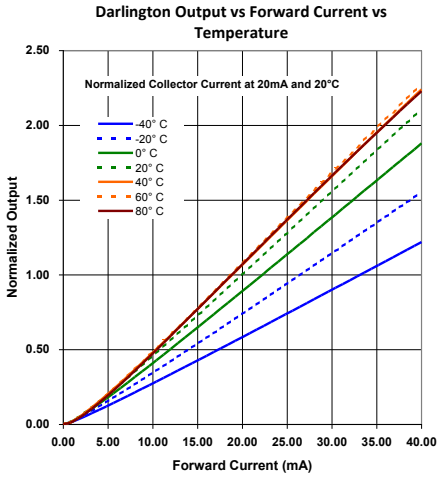






Appendix F

CUI CLF0381MP-1

CUI INC

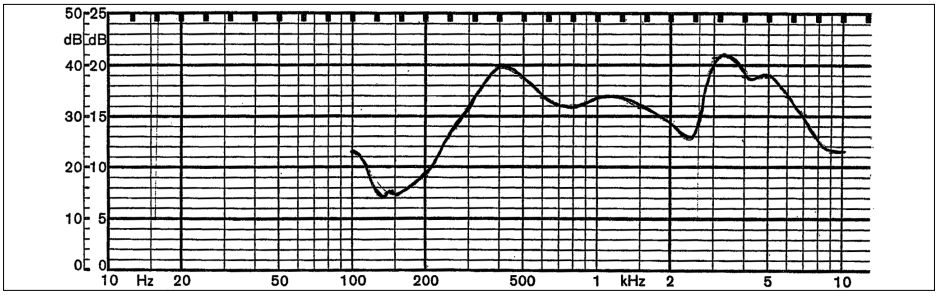
PART NUMBER: CLF0381MP-1 **DESCRIPTION:** speaker

SPECIFICATIONS

nominal size	38 mm		
impedance	8 Ohm ± 15%	at	1 KHz 1 V
resonant frequency	380 Hz ± 76 Hz	at	1 V
sound pressure level	93 dB/w ± 3 dB	0.1 w 5 cm ave. at 0.6K, 0.8K, 1K, 1.2K Hz	
response	Fo Hz ~ 10 KHz max 10 dB		
input power	nominal	0.25 W handling capacity	0.4 W
operation	must be normal at program source 0.25 W		
buzz, rattle, etc.	must be normal at sine wave 1.41 V		
magnet	size: 27 x 17 x 3 mm		
load test	white noise	0.25 W for	48 hours
heat test	70 ± 2° C	20-50% R.H.	48 hours
humidity test	40 ± 2° C	90-95% R.H.	48 hours

FREQUENCY RESPONSE CURVE

potentiometer range	50 dB
rectifier	RMS
lower limit frequency	20 Hz
wr. speed	100 mm/sec



zero level 60 dB

initial here_____

Additional Resources: Product Page | 3D Model

REV.	DESCRIPTION	DATE
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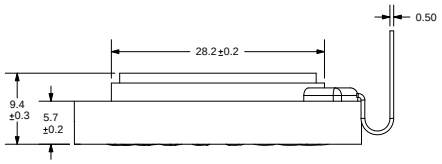
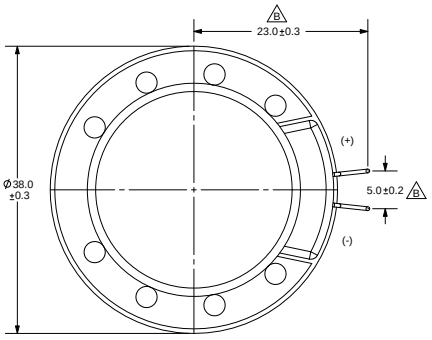
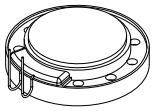
B	Added dimensions	4/2/2008







SCALE 1:1

TOLERANCE:
±0.5mm UNLESS OTHERWISE SPECIFIED

RoHS

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Tualatin, OR 97062
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800-275-4899
Fax: 503-612-2383
Website: www.cui.com

TITLE: LOW PROFILE SPEAKER		REV: B
PART NO. CLF0381MP-1	UNITS: MM [INCHES]	
DRAWN BY: ZRJ	APPROVED BY:	SCALE: 2:1

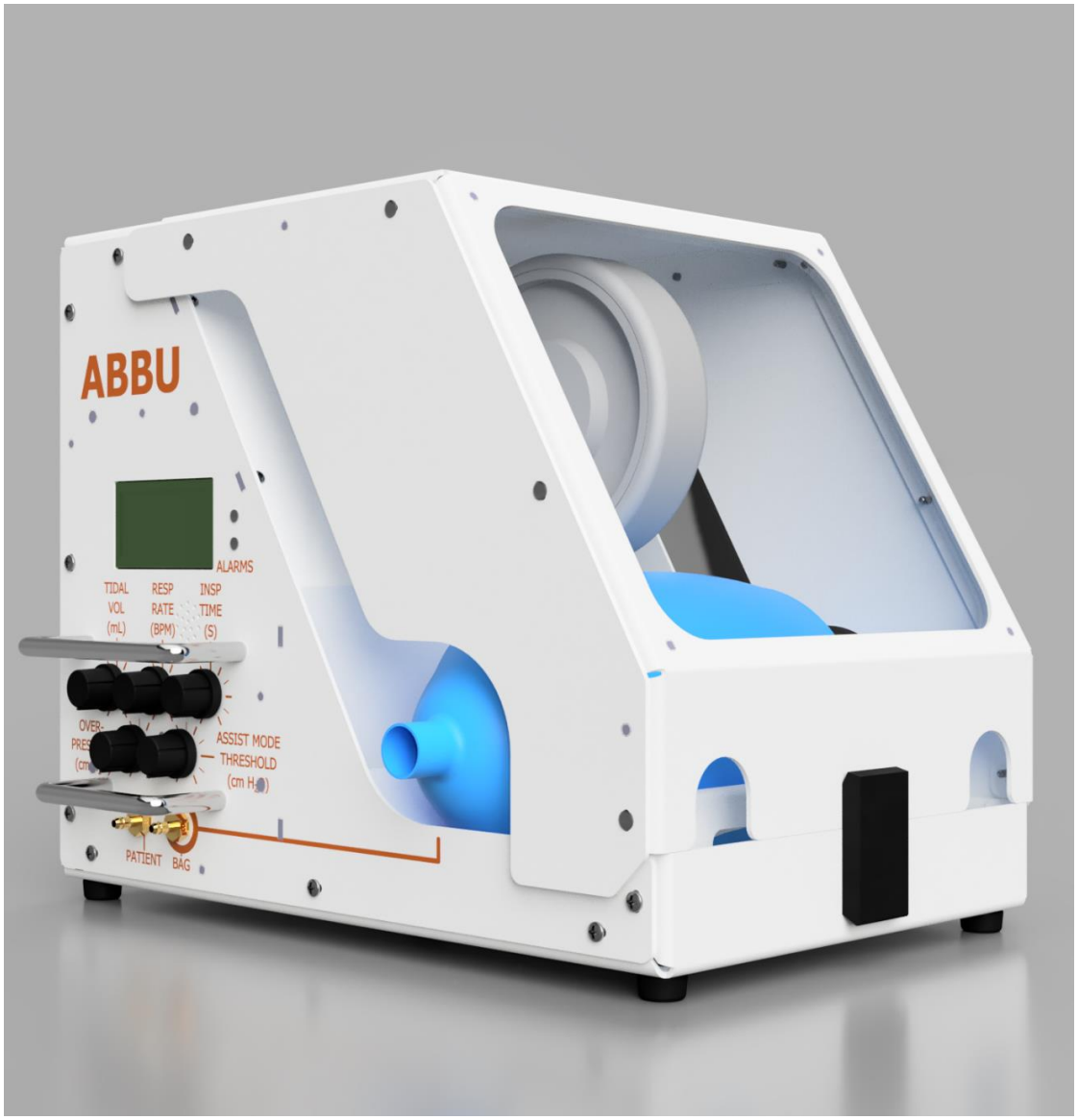
PC FILE NAME: CLF0381MP-1

Appendix G

ABBU Instruction For Use

The Automated Bag Breathing Unit

Instruction For Use



CONTENTS

Introduction

Notice to Operators

The Automated Bag Breathing Unit (ABBU) is designed to replace the manual ventilation of a bag valve resuscitator by a trained professional healthcare provider. The ABBU is intended to provide automated ventilatory support for adult patients who need mechanical ventilation with the use of a bag valve resuscitator. The operators of the ABBU are presumed to be all trained professional healthcare providers and not lay persons. When used with a bag valve resuscitator, ABBU will provide gas exchange support in accordance with lung protective guidelines for management of adult Acute respiratory distress syndrome (ARDS) as recommended by the ARDS Network. ABBU, when used with a bag valve resuscitator, has the capability to use low flow oxygen from a variety of readily available sources (e.g. oxygen concentrators, hospital piped O2 flow meters, oxygen tanks, and liquid oxygen reservoirs). This device is not a full-featured ICU ventilator, but a device that allows automated operation of a bag valve resuscitator, or similar device, with adjustments for critical respiratory parameters. The ABBU is an emergency use resuscitator for use with appropriate critical care monitoring on adults (>18 years of age) requiring mechanical ventilation during declaration of National Emergency where ventilator needs has surpassed ventilator supply and no other ventilatory support devices are available.

⚠ WARNING

- Read the entire manual before using the ABBU device.
- Use the ABBU device only as directed by a physician or healthcare provider.
- Use the ABBU device only for the intended use as described in this manual. Advice contained in this manual does not supersede instructions given by the prescribing physician.
- Install and configure the ABBU device in accordance with the instructions provided in this guide.
- Always secure the ABBU on a flat, stable surface that is free of dirt and debris prior to operation.

Indications for Use

When paired with a bag valve resuscitator, the Automated Bag Breathing Unit is intended to provide continuous or intermittent ventilatory support for the care of the individuals who require mechanical ventilation. ABBU was designed to meet the ventilator shortage caused by the COVID-19 pandemic. The use environment is for institutional use. Institutional use includes ICU or other hospital environments including intra-hospital transport. Please see below for technical information. There is also a quick reference placard available on the device housing.

⚠ CAUTION

- This device is not a full-featured ICU ventilator.
- While the ABBU frees providers from actuating a bag valve resuscitator such as an Ambu bag, the ABBU is not designed to be used without provider supervision. Please ensure that patients are monitored appropriately while the ABBU is providing respiratory support.

ABBU Device Overview

Design Philosophy

To address the ventilator shortage of COVID-19 pandemic, the intent of this design was to enable the rapid assembly of a mechanical device capable of sustaining a person's complete respiration requirements for 10 consecutive days, non-stop. A central feature is its reliance on the traditional self-inflating, adult resuscitation bag. Resuscitation bags are ubiquitous in hospitals, and the process is already verified to be capable of safely and adequately sustaining a patient's ventilation requirements. Our design simply replaces the healthcare provider, who would otherwise need to manually squeeze the resuscitation bag. ABBU frees the healthcare provider to treat other patients. Parts selection was guided by the idea that contract manufacturers should be able to procure every component, either by ordering or purchasing locally within days. Priority for component selection therefore was driven by its prevalence.

Device Summary

When used with a bag valve resuscitator, the Automated Bag Breathing Unit (ABBU) will provide gas exchange support in accordance with lung protective guidelines for management of adult ARDS as recommended by the ARDS Network. Through the bag valve resuscitator, ABBU has the capability to use low flow oxygen from a variety of readily available sources (e.g. oxygen concentrators, hospital piped O2 flow meters, oxygen tanks, and liquid oxygen reservoirs). Direct operator adjustable device parameters include tidal volume, respiratory rate, inspiratory time, and positive end-expiratory pressure. FiO2 is indirectly determined by oxygen flow rate and patient minute ventilation. Patient tidal volume and total respiratory rate may vary from set parameters as the design permits spontaneous breathing throughout the respiratory cycle as an essential safety feature. Although this device does not possess all the adjustable parameters and modes of a full-featured ICU ventilator, it meets the essential requirements of a mass casualty in that it can be rapidly manufactured and deployed to both hospital and non-hospital austere settings. Importantly, operation of the device can be quickly taught to health care providers who may have less clinical experience - as may be needed in the current COVID-19 pandemic.

The device provides both visual and auditory alarms that respond to circuit disconnection, circuit leaks, high airway pressure, and motor-electrical system failure to ensure patient safety. The high visibility device enclosure facilitates rapid troubleshooting of the patient, circuit, and motor-bag valve interface.

Airway circuit components recommended to be used with the ABBU including heat and moisture filter (HME), bacterial-viral filters, Peak End Expiratory Pressure (PEEP) valves, and adult resuscitation bags used for this device are widely available. In the event of device failure, clinicians can rapidly open the see-through enclosure to access the resuscitation bag and provide immediate hand compression bag-valve ventilation. This is a unique safety feature of the design and is critical for use in austere environments. In the unlikely event of bag failure, it can rapidly be replaced with another resuscitation bag to resume device operation.

There are potential risks with all medical devices, however this device has the essential alarm and parameter settings to safely manage the majority of intubated adult COVID-19 patients with ARDS. It can be quickly mass-produced and deployed to assist with the current national and international ventilator shortage due to COVID-19.

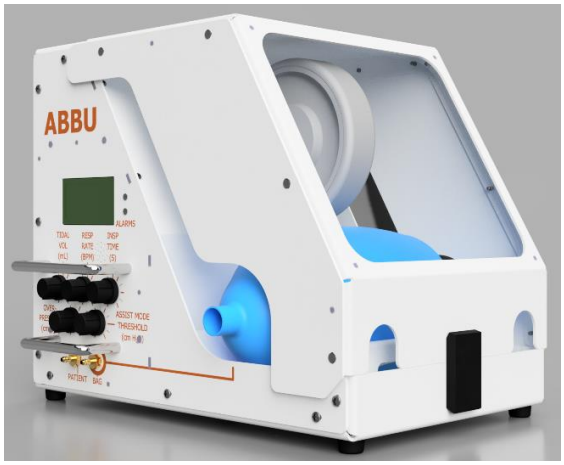


Figure 1. Automated Bag Breathing Unit (ABBU) device.

Figure 2.ABBU device back.

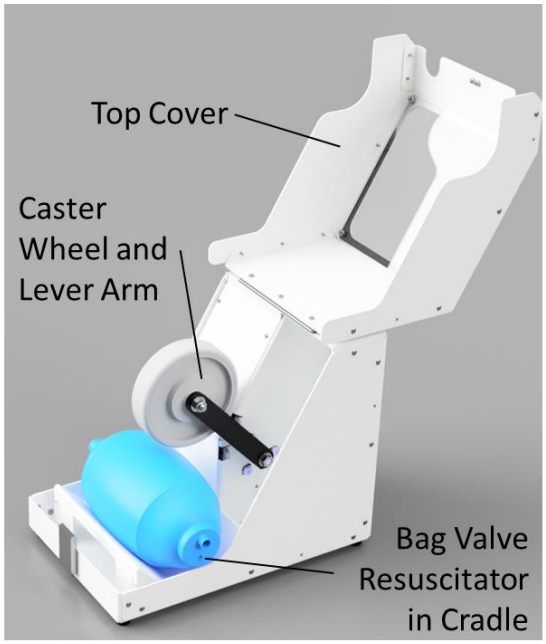


Figure 4. Interior of the ABBU.

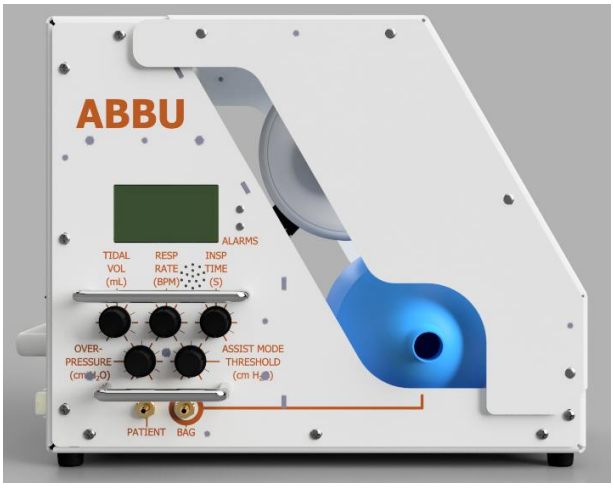


Figure 3. Front panel of the ABBU with adjustment controls.

ABBU Device Specifications

ADJUSTABLE SETTINGS ON THE ABBU FRONT PANEL		
Setting Parameters	**Range**	**Comments**
Respiratory Rate (BPM)	Up to 40	Set BPM 10 to 40 BPM. When in assist mode, ABBU will support up to 60 BPM.
Tidal Volume (mL)	200-800	
Inspiration Time (s)	0.5 to 2.0	At 2s inspiratory time, the respiratory rate is limited to a max breath rate of 20 BPM. Inspiration time cannot exceed the set respiratory cycle time less 0.3 seconds.
Over-pressure (cmH20)	50 to 70	
Assist mode threshold (cmH20)	-1 to -10	
TECHNICAL INFORMATION		
	Details	**Comments**
Control	Operating Mode: Assist Control Primary Control: Volume	

Rate	Peak Flow Rate: 0.2 – 1.5 L / s Breath Rate: up to 50 Breaths/min	For lung compliance of 0.07 L/cm H20 and inspiration time =1.0s
Pressure	Peak Inspiratory Pressure (PIP): 40-55 cm H20 Peak End Expiratory Pressure (PEEP): 18-22 cm H20	For lung compliance of 0.02 to 0.07, TV =400mL, Inspiration Time = 1.0s (1 hPa=1.019744 cm H20)
Volume	Tidal Volume (TV): 200 – 800 mL Minute Ventilation: 2 – 40 L/min	
Time	Inspiratory Time: 0.5 – 2.0 sec Expiratory Time: 0.4 – 5.5 sec	At 2s inspiratory time, the respiratory rate is limited to a max breath rate of 20 BPM. Inspiration time cannot exceed the set respiratory cycle time less 0.3 seconds.
Supplemental O2	Input Flow Rate: 5-15 Liters/min FIO2: 21-98%	
Operating Time	At least 12 days	Base on motor durability test
Alarms	Underpressure (Low Airway Pressure) Overpressure (High Airway Pressure) Loss of Power Tidal Volume Out of Spec Motor End of Life System Failure	Nonadjustable, <3 cm H20 Adjustable from 50 to 70 cmH2O - >100mL deviation - -
Operating Temperature	Up to 40C (104F) Similar to other ventilator devices.	Not to be used in extreme temperature environment.
Operating Relative Humidity	Relative Humidity 15 to 95%, noncondensing	Refer to power supply
Cooling	Fan and cooling vents	
Power Supply	220W 110-240VAC to 12VDC Operating Temperature 0 – 60°C Storage Temperature 40°C to +85°C Relative Humidity 15 to 95%, noncondensing	Medical Approval EN606011 Class I 3rd Edition; CEC Compliant
Operating Altitude	<8000 ft	Input from clinician.
Recommended Resuscitator Bag	Ambu SPUR II	Recommended operating temperature: -18° C to +50° C Storage Tested at -40° C and + 60° C according to EN ISO 10651-4
Setting Parameters	TIDAL VOL (mL) RESP RATE (BPM) INSP TIME (s) OVER-PRESSURE (cmH2O) ASSIST MODE THRESHOLD (cmH2O)	Adjustment settings on ABBU front panel.
Oxygen Ports	PATIENT: 3/16" ID tube connection from ABBU to patient BAG: 3/16" ID tube connection from ABBU to bag resuscitator	

ABBU Front Panel Interface

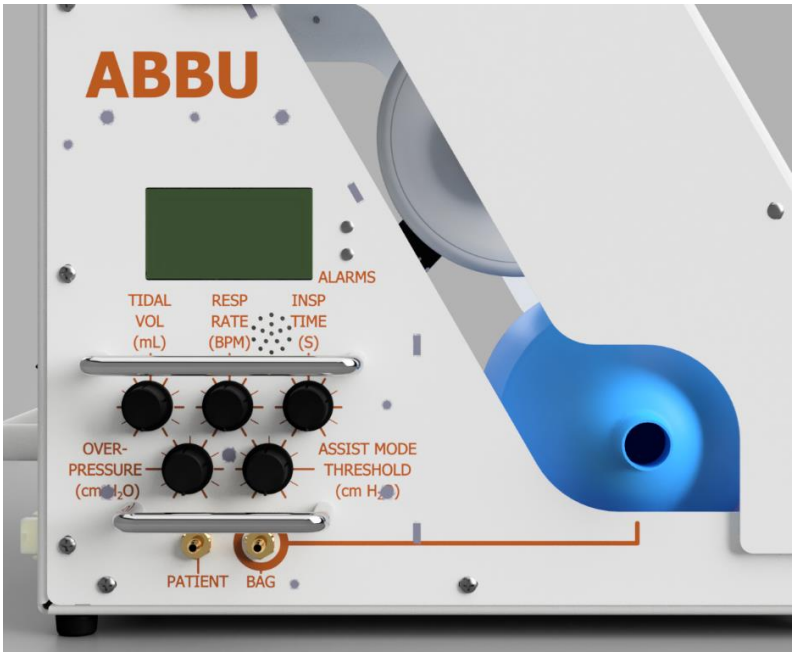


Figure 5. ABBU ventilation settings.

Ventilation Setting Adjustment

The ABBU has five adjustment knobs for changing the settings.

- TIDAL VOL: The tidal volume is adjustable from 200-800 mL.
- RESP RATE: Respiratory Rate has a range up to 50 breaths per minute.
- INSP TIME: Inspiratory time can range from 0.5-2.0 seconds.
- OVER-PRESSURE: This adjusts the overpressure alarm threshold from 51 to 70 cmH2O.
- ASSIST MODE THRESHOLD: Adjustment for patient assist mode response from -5 to -8 cmH2O.

Oxygen Tube Connections

There are two oxygen tube connectors with one connection supplying to the patient and the other connection going to the bag valve resuscitator.

- PATIENT: 3/16” ID tube connection from ABBU to patient

- BAG: 3/16” ID tube connection from ABBU to bag resuscitator

Figure 6. Oxygen tube connectors on the ABBU.

LCD Display

The LCD panel shows the following information:

- All “cm” units are abbreviated for cmH2O.
- TIDAL VOL, RESP RATE, INSP TIME, and OVER-PRESSURE are set by the adjustment knobs on the ABBU front panel. OP is the abbreviation for OVER-PRESSURE on the LCD display.
- The current patient pressure is shown with “p” and the value by it.
- The total patient breathing rate is displayed as a value with “tot.bpm”. “tot.bpm” is the total breath per minutes.
- PP is the estimated Peak Inspiratory Pressure.
- PEEP is the estimated Positive End-Expiratory Pressure.
- The ASSIST MODE THRESHOLD will display when the user makes an adjustment on the knob.
- Alarms and warnings are displayed on the top most line of the LCD display.

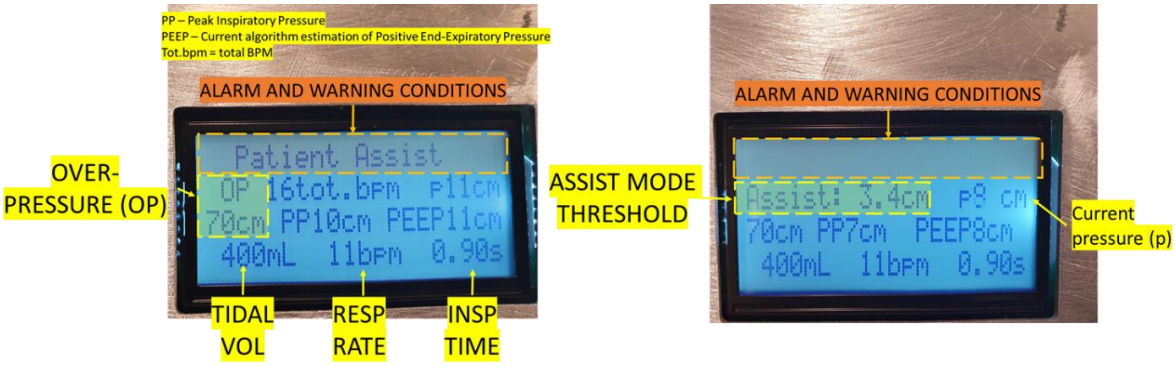


Figure 7. Readout on ABBU LCD display.

ABBU Power Management

The ON/OFF Switch is used to activate the ABBU device once it is plugged into main AC. Please check that the power switch is in the OFF position before plugging into the main AC wall outlet. The ABBU power supply is a 220W 110-240VAC to 12VDC medical grades supply. The ABBU is intended to only be used when connected to a power outlet. The ABBU enclosure has a panel mount power adapter that accepts the plug from the external power supply and is designed according to United States standards. In the event of a loss of power, a 9 Volt, alkaline battery will enable a red flashing LED and auditory alarms and display POWER LOSS.

⚠ WARNING

- Replace the 9V alkaline battery after a power loss event has occurred or change out the battery every 12 months.
- Beware of electrocution. Do not immerse the device, power supply or power cord in water.
- Inspect to make sure the power cord and plug are in good condition and the equipment is not damaged.
- Keep the power cord away from hot surfaces.
- Ensure that the power cord does not pose a tripping or choking hazard.
- If the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power source.
- Do not use extension cords, adapters, or power cords that are not approved for use with ABBU.

Figure 8. Power management.

Patient Respiratory Circuit

Bag Valve Resuscitator

The ABBU was tested with the Ambu SPUR II bag valve resuscitator. The recommended use duration for the Ambu SPUR II is up to seven days. Durability data when using this Ambu bag is located in the Appendix. Below are the material and technical specification of the Ambu Spur II as provided by the manufacturer, Ambu.

AMBU SPUR II MATERIAL SPECIFICATION	
Product	**Material**
Bag	SEBS
Patient valve housing	Styrene Butadiene
Patient valve housing locking ring	Poly Carbonate
Expiratory connector	Styrene Butadiene
Splash guard	SEBS
Swirl	20% glass filled Poly Propylene
M-Port	Styrene Butadiene
M-Port insert	Styrene Butadiene
M-Port cap	Santoprene
Manometer port gap/tube adaptor	Poly Ethylene
Valve disc	Silicone
Inlet valve assembly	Styrene Butadiene
Inlet valve assembly glue	Modified Urethane Acrylate UV adhesive
O2 reservoir	Bag: Poly Ethylene Tube*: Poly Ethylene
O2 tube	PVC (Phthalate Free)
Pressure limiting valve spring	ABS
Pressure limiting valve spring	Stainless Steel

AMBU SPUR II ADULT TECHNICAL SPECIFICATION	
Stroke volume	one hand 600 mL/ two hands 1000 mL
Resuscitator volume	1475 mL
Dimensions (length x diameter)	295 x 127 mm
Weight incl. reservoir O2 tube/mask	314 g
Pressure-limiting valve	Pressure limiting valve*: 4.0 kPa (40 cmH2O)
Dead space	<6 mL
Inspiratory resistance without O2	Max. 0.50 kPa (5.0 cmH2O) at 50 l/min
Expiratory resistance	Max. 0.27 kPa (2.7 cmH2O) at 50 L/min
Bag reservoir volume	2600 mL
Patient connector: Outside	22 mm male (ANSI/ISO)
Patient connector: Inside	15 mm female (ANSI/ISO)
Expiratory connector (for PEEP valve attachment)	30 mm male (ISO)
Forward and backward leak	Not measurable
M-Port	Standard Luer LS 6
Recommended operating temperature	-18° C to +50° C
Storage	Tested at -40° C and + 60° C according to EN ISO 10651-4


WARNING

- Our breathing unit can reasonably be used with other similar bag valve resuscitators, which are abundantly available in clinical settings. Replacement duration of the bag valve resuscitator will vary with manufacturer of the bag valve resuscitator. Monitor ABBU closely when using non-Ambu SPUR II bag valve resuscitator to determine bag durability.

Figure 9. Example of bag valve resuscitator. Shown is the Ambu SPUR II.

Breathing Circuit Configuration

The ABBU is used with a 6 foot breathing circuit. Components for the breathing circuit is not provided. The healthcare provider will need locate the components below at their facility to assemble the breathing circuit. The components are list in sequence of assembly from the patient side to the ABBU side.

1. ETT or Tracheostomy Tube
2. in-line suction device
3. 6" flex tube
4. in-line nebulizer adapter or MDI adapter (optional)
5. HME filter
6. HEPA bacterial-viral filter (if not using combo HME-HEPA)
7. Patient airway pressure sensing line
8. Mainstream ETCO2 adapter
9. O2 sensor
10. Patient exhalation valve with manual PEEP adjustment valve
11. Patient manual PEEP valve set to 5 cmH2O (for initial start up)
12. Pressure pop-off valve (optional)
13. 6 foot, 22mm ID circuit tube
14. Bag pressure sensing line
15. Bag with patient exhalation valve and manual bag PEEP valve
16. Bag PEEP valve set to 0 cmH2O (full open, while operating ABBU)
17. O2 reservoir bag or corrugated tubing

18. O2 source (1-15 LPM) connected to Bag

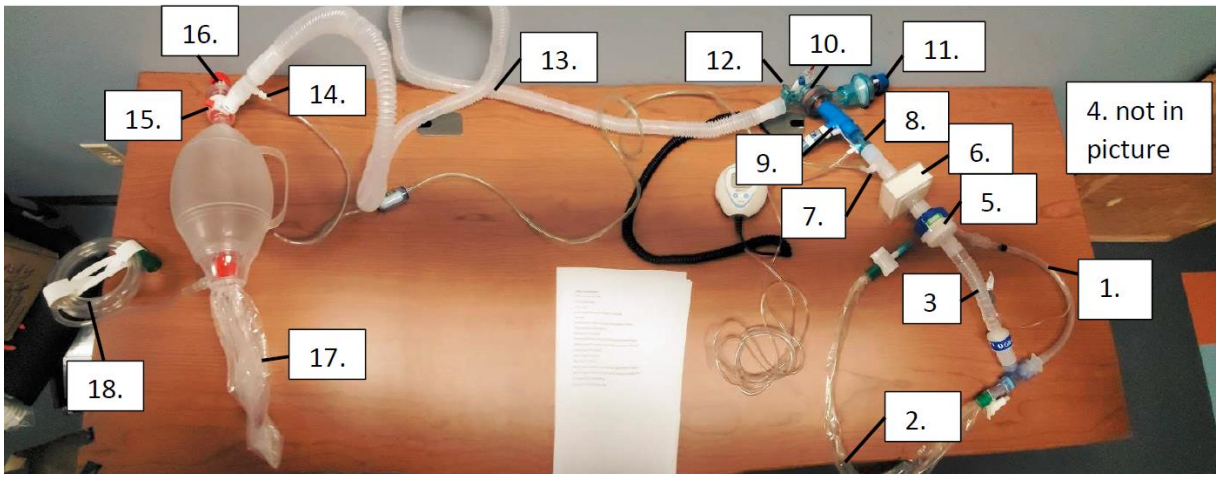


Figure 10. Breathing circuit.

WARNING

- Only use FDA compliant components in the breathing circuit that are biocompatible to ISO 18562 and ISO 10933 standards.
- The patient circuit should be arranged so as not to restrict movement or pose a strangulation risk.
- Do not use electrically conductive or anti-static air tubing to reduce risk of fire.

Using the ABBU

Using the ABBU for the First Time

When using the ABBU device for the first time, first perform a functional test. A functional test will ensure the device is in proper working order before starting therapy. To prevent possible damage to the ventilator, always place the ABBU on a flat, stable surface that is free of dirt and debris.

To perform a functional test:

1. Turn off the device using the power switch at the back of the device.
2. Check the condition of the device and accessories by inspecting the device and all accessories. Damaged components should not be used.
3. Check the patient circuit setup. Check the integrity of the patient circuit and that all connections are secure.
4. Turn on the device and test alarms.

Powering On the ABBU

1. Check that the rocker switch on the back of the ABBU is in the off position.
2. Connect the DC plug of the supplied external power supply unit to the rear of the ABBU device.
3. Before connecting the power cord to the power supply unit, ensure the end of the connector of the power cord is correctly aligned with the input socket on the power supply unit.
4. Plug the other end of the power cord into the power outlet.
5. To turn on the ABBU, move the rocker switch to the on position. This will start ventilation.

Powering Off the ABBU

1. Do not turn the ABBU off by unplugging the power cord from the power outlet or unplugging the DC connector from the rear of the ABBU.
2. To turn the ABBU off, move the rocker switch to the off position. This will stop ventilation.

⚠ WARNING

- The power loss alarm will be activated when the ABBU is unplugged from the power outlet or the DC connector is unplugged from the ABBU while the ABBU is turned on.

Installing and Securing Bag Valve Resuscitator

1. Center the bag valve resuscitator within the AMBU bag cradle.
2. Secure both ends of the bag valve resuscitator as shown with the cord provided to the J-hooks on the cradle.

Insert image of cord and hooks.

ABBU Ventilation Setup and Operation

1. Install adult-size bag valve resuscitator into ABBU and setup circuit (see Figure 10. Breathing circuit.).
2. Attach patient and bag pressure monitoring tubes to “Patient” and “Bag” connectors on ABBU.
3. Set Bag PEEP valve to fully open position [PEEP = O cmH2O].
4. Connect oxygen source [flow rate 5 -15 lpm] to bag valve resuscitator reservoir.
5. With ABBU power switch “off”, plug power supply into ABBU and external 100-240 AC outlet.
6. Turn ABBU power switch “on”.
7. Set Tidal Volume 6-8 mL/kg/IBW [setting range: 200-800 mL].
8. Set Respiratory Rate 12-15 bpm [setting range: 10-40 bpm].
9. Set Inspiratory Time 1 second [setting range: 0.5-1.5 s].
10. Set Over Pressure Alarm [setting range: 50 - 70 cmH2O].
11. Set Assist Mode Threshold to -2 cmH2O.

12. Occlude circuit at patient end and verify high pressure alarm activates and lever bar inside the ABBU retracts (may require 3 to 4 breaths to reach pressure threshold). Open circuit and verify that low pressure alarm activates and bar continues to cycle.
13. Attach circuit to patient endotracheal tube.
14. Adjust manual PEEP valve at patient connection to desired PEEP using ABBU digital pressure display [setting range: 5-20 cmH2O]
15. Adjust Assist Mode Threshold [setting range: -1 to -10 cmH2O] to optimize patient triggering synchrony.
16. Monitor patient pulse oximetry, ETCO2, BP, HR, cardiac rhythm, total respiratory rate, inspiratory effort, and patient-ABBU synchrony.
17. Monitor ABBU Peak Airway Pressure and PEEP on ABBU digital display.
18. Estimate FiO2 delivery using Table or measure with FiO2 analyzer.
19. Check ABG or VBG within 15 minutes of patient connection to ABBU.
20. Replace HME and HEPA filter if visible secretions is observed.

(ETCO2 = end-tidal CO2, BP = blood pressure, HR = heart rate, ABG = arterial blood gas, VBG = venous blood gas, HME = heat and moisture filter, bacterial-viral filters, PEEP = Peak End Expiratory Pressure)

Insert FiO2 table at TV of 400mL

⚠ WARNING

- When the PEEP valve is adjusted, the Assist Mode Threshold may need to be adjusted to minimize auto triggering or asynchronous breathing. The adjustment will take 3 to 5 breaths for a pressure change to response on the LCD display.
- Use only medical grade oxygen sources.
- Oxygen flow must be turned off when the device is not ventilating so that oxygen does not accumulate within the device enclosure. Accumulation of oxygen presents a risk of fire.
- Oxygen supports combustion. Oxygen must not be used while smoking or in the presence of an open flame. Only use oxygen in well-ventilated rooms.
- The patient circuit and the oxygen source must be kept away from any sources of ignition.
- Check on volume of the capnography for evidence of rebreathing.
- To reduce the risk of CO2 rebreathing, monitor the patient for changes in respiratory status at the start of ventilation and with each change in the breathing circuit configuration or introduction of new component, ABBU settings, or patient condition.
- To reduce the risk of electric shock from liquid entering the device, do not put a container filled with a liquid on the ventilator.

Bag Valve Resuscitator Usage Time

The motor count can be used to determine the bag valve resuscitator usage. Turning the RESP RATE knob to the left will show the absolute motor count.

When installing a new bag valve resuscitator, record the motor count value and this will be the beginning value. Before replacing the current bag valve resuscitator, record the motor count value and this will be the ending value. The difference in the value will be the duration of use based on motor cycle.

Patient Assist Mode

Need explanation and operation of assist mode. Also, differentiate from MIT eVent's assist mode.

Alarms

Alarm Priority

Alarms are classified into relative priority according to severity and urgency. Respond to all alarms. An immediate response if required for high priority alarms.

Alarm Priority	Alarm LED Color	Audible Alert
High	●	Yes, ccc-cc pattern
Low	●	Yes, ccc pattern

ABBU Alarm Summary

Alarm	**Alarm Priority**	**Alarm Activation**	**Corrective Actions**	**LCD Message**	**Default Alarm Settings (e.g. latched, not latched alarm signals, alarm condition disabled)**
Loss of Power	**high priority, general audio ccc-cc**	Measure 12V line for when power goes to 9V using battery.	- Check the patient's status and airway. - Manually bag patient as needed. - Check ABBU is plugged into power outlet. - Replace 9V battery after each power loss event. - If problem persists, provide alternative ventilation. - Contact manufacturer.	Power Loss	Latched; re-power device
Overpressure (high airway P)	**high priority, general audio ccc-cc**	Setting is adjustable between 50 to 70 cmH2O. If above setpoint, alarm is activated.	- Check the patient's status and airway. - Check for obstruction in patient or breathing circuit. - Manually bag patient as needed. - If no obstruction, alert and consult with doctor. - Adjusting setting to higher value will stop the alarm. - If problem persists, provide alternative ventilation.	Overpressure	Unlatched

			- Contact manufacturer.		
Underpressure (low airway P)	**high priority, general audio ccc-cc**	When pressure sensor detects <3 cmH2O, the alarm will activate. Value not adjustable.	- Check the patient's status and airway. - Manually bag patient as needed. - Alert and consult with doctor. - Check for break or leak in breathing circuit or bag valve resuscitator. - Replace bag valve resuscitator as needed. - If problem persists, provide alternative ventilation. - Contact manufacturer.	Underpressure	Unlatched

System Failure	**high priority, general audio for SW failure, ccc-cc**	Alert for Watchdog SW. After 3 attempt to home, the alarm will activate.	- Check the patient's status and airway. - Manually bag patient as needed. - Turn the power off and then on. - If problem persists, provide alternative ventilation. - Contact manufacturer.	Critical Software or Hardware Error Detected Replace Unit NOW!	SW will attempt to reset
Tidal Volume Out of Spec (not met or exceed)	**low priority, general audio ccc**	When lever arm position has >100mL deviation, the alarm is activated.	- Check the patient's status and airway. - Manually bag patient as needed. - Adjust the tidal volume. - Check bag valve resuscitator is seated properly and secured in cradle. - Replace bag valve resuscitator as needed. - Alert and consult with doctor. - If problem persists, provide alternative ventilation. - Contact manufacturer.	Tidal Vol. Not Met	Unlatched

Motor end of life	**No sound, No LED**	When home count, passes the threshold number of counts.	- Check the patient's status and airway. - Manually bag patient as needed. - Contact manufacturer.	Warning: Motor EoL	Latched, require factory reset

 WARNING

- If an alarm activates repeatedly, discontinue use, switch to a backup ABBU and return the device for servicing.

General Warnings

- In the event of a power or device failure, open the ABBU device to access the bag valve resuscitator for manual operation.
- Do not use the same bag valve resuscitator in the ABBU for more than 7 days. Replace bag valve resuscitator after a maximum 7 days of operation, or between patients, whichever comes first.
- Displayed Tidal Volumes are approximated volumes delivered to the patient (not measured by the ABBU).
- This Resuscitator relies on the integrity of the protective earth ground to reduce the risk of electrical shock. Check the integrity and verify the function of the protective earth ground of the supply mains receptacle prior to use.
- Some ventilation modes allow synchronization with spontaneously breathing patients using triggering algorithms. This device incorporates such triggering algorithms for spontaneously breathing patients some potential risks for inadequate triggering algorithms include missed triggers, trigger delay, auto-triggering, and breath stacking. Asynchrony between the mechanical ventilator and patient effort can result in adverse health outcomes including increased time on the ventilator, hospitalization, and mortality.
- Due to the rapid development cycle for this emergency use device, all efforts were made to verify the software, but defects may still exist. The consequences of these defects are unknown and may pose a risk to the patient.
- Center the bag valve resuscitator in the ABBU device such that the center of the bag is directly underneath the actuator wheel before using. 104

- Inspect bag valve resuscitator for defects before using in the ABBU device
- Place the ABBU on a flat surface before operating.
- Keep ABBU cover closed during normal operation.
- Read the instruction manual before using
- Patient monitoring is required when operating the ABBU.
- SpO2 and PetCO2 monitoring is required when operating the ABBU.
- FiO2 delivery is approximated and will vary depending on O2 flow rate and patient minute ventilation (see FiO2 Table Decal).
- Ensure that the pressure sensor tubing is attached to the ABBU circuit at all times.
- To achieve proper tidal volume, ensure that the bag valve resuscitator is centered lengthwise underneath the ABBU arm.
- When using an external power adapter, connect the ABBU to a 12 V 300W medical grade power source.
- Ensure that a Heat Moisture Exchanger (HME) is connected to the endotracheal tube, followed by the exhalation valve and exhaled air filter (see Airway Circuit Diagram Decal)
- To reduce the risk of CO2 rebreathing, monitor the patient for changes in respiratory status at the start of ventilation and with each change in ventilation settings or patient condition.
- Be aware of the possibility of contamination from patient exhalation being exhausted into ambient room air through the exhalation port.
- Use infectious airborne environmental precautions and personal protective equipment as appropriate
- This ventilator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.
- A nurse call/remote alarm should be considered a backup to the ABBU's primary alarm system.
- To reduce the risk of fire, use the ABBU in a well-ventilated area away from flammable anesthetics. Do not use ABBU near an open flame.
- Do not use ABBU in a hyperbaric chamber or for aeromedical transport.
- To prevent possible patient injury, always return airway pressure alarm settings to recommended values after a preoperational check.
- This Resuscitator has not been tested for electromagnetic compatibility (EMC). It may produce electromagnetic disturbances that will affect the performance of other equipment. It may fail to perform as expected in the presence of electromagnetic disturbances from other equipment.
- Use only FDA approved non-conductive components to construct the breathing circuit.
- ABBU is not a transport operable emergency use resuscitator system. Do not move ABBU while it is operating.
- If a burning odor or spark is observed, turn off the system and contact manufacturer.
- Power off the ABBU when changing out the 9V battery.
- User must shield speaker and cooling fan holes from water ingress.
- Keep the system and its gas hoses clear of all ignition sources.
- Do not use the system with worn or frayed hoses or hoses that have been contaminated by combustible materials such as grease or oil.
- Oxygen-enriched gas is extremely flammable: if you detect a burning odor, disconnect the oxygen supply to the ventilator and turn off the system.
- Do not insert any foreign object into any part of the ABBU system.

- Keep hands and fingers away from moving parts or while ABBU is operating.
- To prevent possible asphyxia and to reduce the risk of CO2 rebreathing, take these precautions with respect to mask and exhalation port use:
    - Do not operate the ABBU without a connected Oxygen source
    - Do not occlude the exhalation port.
    - Turn on the ABBU and verify that the exhalation port is operational before application.
    - To ensure the ABBU's safe operation, always run a full preoperational check before patient use. If ABBU fails any tests, remove from clinical use immediately. Do not use the ABBU until necessary service is completed and all tests have passed
- In order to avoid Adiabatic compression when used with oxygen:
    - Use only original equipment and spares when handling/ servicing oxygen equipment.
    - Open and close oxygen cylinder top valves before connecting equipment. This in order to remove any foreign items and hence preventing them entering the system.
    - Work clean. No oil or impurities must contaminate the parts (your hands, tools etc.).
    - Open oxygen cylinder top valves slowly.
-

ABBU Decal Signage

There will be two placards placed as stickers on the device: a list of warnings below, and a placard that diagrams the default airway circuit and the expected FiO2 values for various respiratory parameters.

Decal on ABBU Back Panel

There are two decals on the ABBU back panel providing general user warnings and information. The information on the decals will show the content below for each decal.

General Warnings Decals

This decal has the following statements printed on the decal.

General Warnings

- This emergency use resuscitator is for use with appropriate critical care monitoring on adults (>18 years of age) requiring mechanical ventilation during declaration of National Emergency where ventilator need has surpassed ventilator supply and no other ventilatory support devices are available.
- Read the instruction manual before use.
- If power fails, lift lid and operate bag manually.
- Keep ABBU cover closed during normal operation.
- Use a 220W 110-240VAC to 12VDC medical grade power supply.
- Do not move the ABBU or bag valve resuscitator during operation and connected to the patient.

Manufacturer Decal

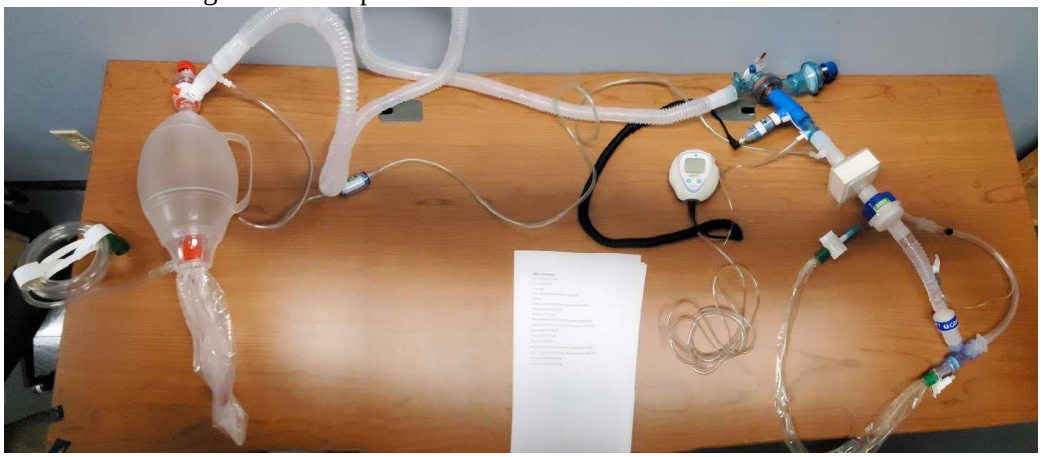
The manufacturer will provide a label to accompany the ABBU device. Please refer as needed to this label for model number, manufacturer name, and contact information.

Decal on ABBU Top Panel

There are two decals on the ABBU top panel providing general user warnings and information on the breath circuit and settings guidance. The information on the decals will show the content below for each decal.

Decal 1 will have the content below:

- Always CENTER bag valve resuscitator underneath ABBU caster lever arm.
- Use breathing circuit as depicted below



Decal 2 will have the FiO2 guidelines for ventilation
Insert FiO2 table at TV of 400mL

Decal on ABBU Front Panel Cover

This decal provides general ABBU setup and operation guidance. The information on the decals will show the content below on the decal.

1. Install adult-size Bag into ABBU and setup circuit
2. Attach patient and bag pressure monitoring tubes to “Patient” and “Bag” connectors
3. Set Bag PEEP valve to full open position [PEEP = O cmH2O]
4. Connect oxygen source [flow rate 5 -15 LPM] to Bag reservoir
5. With ABBU power switch “off”, plug power supply into ABBU and external 100-240 AC outlet.
6. Turn ABBU power switch “on”
7. Set Tidal Volume 6-8 mL/kg/IBW [200-800 mL]
8. Set Respiratory Rate 12-15 bpm [10-40 bpm]

9. Set Inspiratory Time 1 second [0.5-1.5 seconds]
10. Set Over Pressure Alarm [50 - 70 cmH2O]
11. Set Assist Mode Threshold - 2 cmH2O
12. Occlude circuit at patient end and verify high pressure alarm activates and bar retracts (may require 3-4 breaths to reach pressure threshold). Open circuit and verify that low pressure alarm activates and bar continues to cycle.
13. Attach circuit to patient endotracheal tube
14. Adjust manual PEEP valve at patient connection to desired PEEP using ABBU digital pressure display [5-20 cmH2O]
15. Adjust Assist Mode Threshold [range: -1 to -10 cmH2O] to optimize patient triggering synchrony
16. Monitor patient pulse oximetry, ETCO2, BP, HR, cardiac rhythm, total respiratory rate, inspiratory effort, patient-ABBU synchrony
17. Monitor ABBU Peak Airway Pressure and PEEP on ABBU digital display
18. Estimate FiO2 delivery using Table or measure with FiO2 analyzer
19. Check ABG or VBG within 15 minutes of patient connection to ABBU
20. Replace HME and HEPA filter if visible secretions

Cleaning the ABBU

When using the ABBU with a bag valve resuscitator, the following components of the device will make contact with the patient's expired gases and/or bodily fluids and are single-use only and disposable after use:

- Inline respiratory bacteria/virus filters
- All respiratory tubing
- Bag valve resuscitator (which the device actuates to deliver breaths)
- All associated pressure valves, PEEP valves, and one-way flow valves
- Airway pressure sensor

The remainder of the device can be sanitized using antiseptic wipes. The ABBU should be cleaned and disinfected before and after each use, following the latest CDC guidelines on cleaning surfaces specifically related to the virus that causes COVID-19.

Safely disconnect the ABBU power cord from the wall socket before cleaning. After wiping the unit down with cleaning solution, let the unit to dry before use or putting it away.

The following is a list of solutions from the CDC website.

- Isopropyl Alcohol: 70% IPA
- Bleach Solution
    - 5 tablespoons (1/3 cup) bleach per gallon of water OR
    - 4 teaspoons bleach per quart of water

 WARNING

- To prevent possible damage to the ABBU, do not drip or spray any liquids directly onto any surface.
- Do not attempt to sterilize or autoclave the ABBU.
- Do not immerse the device or power cord in water.
- Refer to the specific bag valve resuscitator manual for any additional maintenance and cleaning information.

Contact Information

For additional information, please contact:

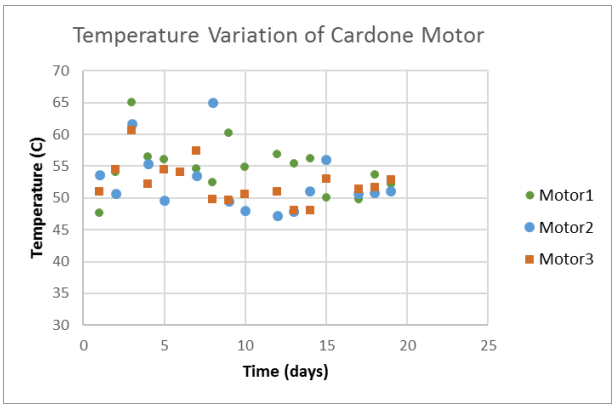
The University of Texas at Austin - Office of Technology Commercialization
West Pickle Research Building (WPR), Suite 1.9A, 3925 W Braker Ln, Austin, TX, 78759
Email Address: licensing@otc.utexas.edu
Phone Number: 512-471-2995

Designed by The University of Texas at Austin, Cockrell School of Engineering

Appendix A

Lever Arm Motor Performance Data

	Motor Temperature (C)		
Day#	**Motor1**	**Motor2**	**Motor3**
1	47.6	53.6	51
2	54	50.6	54.4
3	65	61.6	60.6
4	56.4	55.3	52.2
5	56	49.6	54.4
6			54
7	54.6	53.4	57.4
8	52.4	65	49.8
9	60.2	49.5	49.6
10	54.8	48	50.6
11			
12	56.8	47.2	51
13	55.4	47.8	48

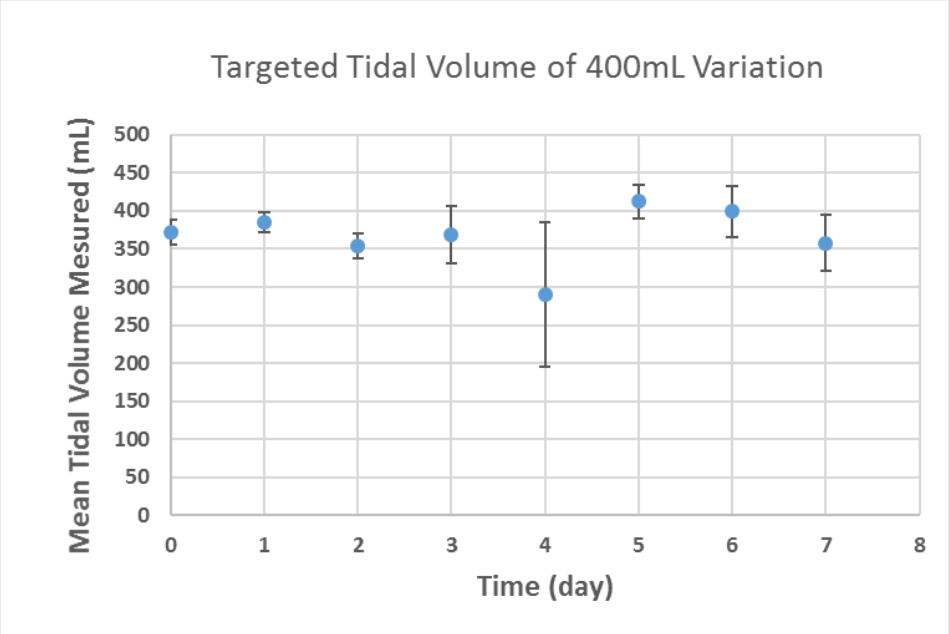


14	56.2	51	48
15	50	56	53
16			
17	49.8	50.6	51.4
18	53.6	50.8	51.6
19	52.2	51	52.8
20			

Ambu Bag Valve Resuscitator Performance Data

This is the durability data for the Ambu SPUR II adult bag valve resuscitator.

	Measured			STDEV		
Day	PEEP (cmH2O)	PIP (cmH2O)	Tidal Volume (mL)	PIP	PEEP	Tidal Volume
0	21.0	41.2	357.5	6.4	3.2	36.6
1	21.2	42.0	371.1	6.3	5.5	37.8
2	21.4	41.4	357.4	5.7	5.7	33.8
3	21.6	43.4	387.2	6.0	5.9	44.9
4	23.5	43.8	289.9	7.7	4.8	94.7
5	25.4	44.8	412.2	7.4	5.8	21.4
6	21.4	44.2	399.3	7.4	6.2	33.9
7	27.3	48.6	357.9	6.4	5.3	37.2



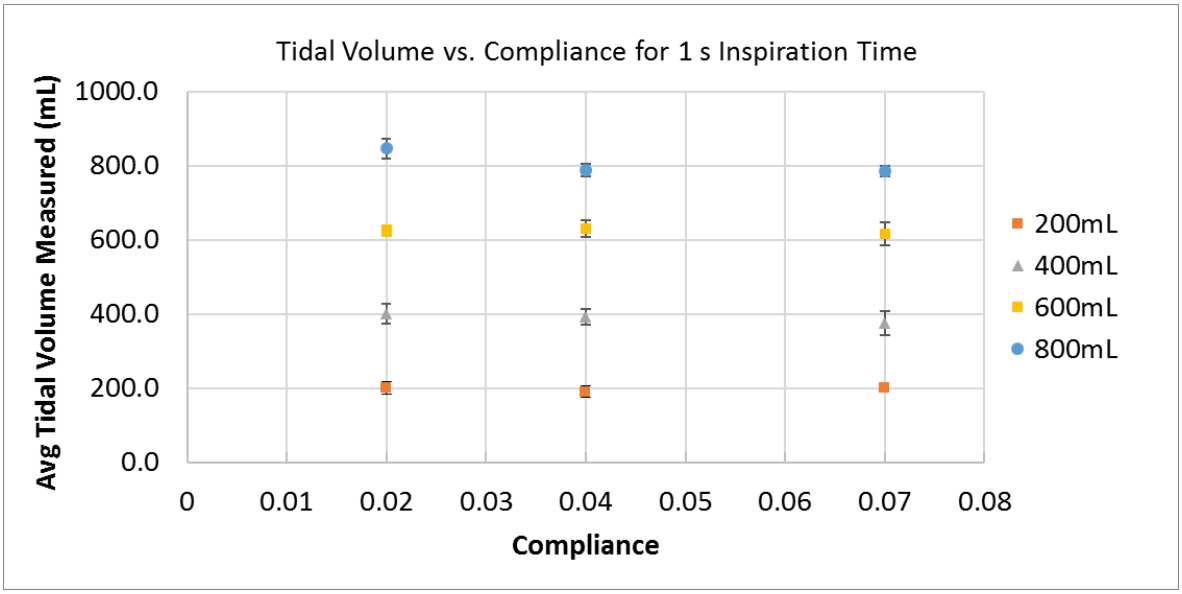
Other Bag Valve Resuscitator Performance Data

			Day							
Bag type	**Set Tidal Volume (mL)**	**Measured Tidal Volume**	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
AmbuBag	400	Mean -->	357.5	371.1	357.4	387.2	289.9	412.2	399.3	357.9
		STD -->	36.6	37.8	33.8	44.9	94.7	21.4	33.9	37.2
Medline	400	Mean -->	406.0	366.8	406.0	394.9	-	-	260.1	-
		STD -->	43.6	41.7	43.6	65.8	-	-	204.5	-
Hudson	400	Mean -->	418.8	418.8	-	450.6	-	-	444.1	-
		STD -->	52.9	53.3	-	34.8	-	-	32.1	-
Mercury	400	Mean -->	383.6	316.9	313.9	-	-	-	-	-
		STD -->	215.7	178.7	179.4	-	-	-	-	-

ABBU Performance Data

PIP, PEEP, and Tidal Volume Response

Evaluation of Targeted Tidal Volume, Pressure, and Flow Rate of ABBU										
Operating Setpoint						Data Measured				
LUNG COMPLIANCE (L/cm H2O)	MICHIGAN LUNG resistance (cm H2O / L/sec)	TIDAL VOLUME (mL)	RESPIRATORY RATE (BPM)	MANUAL PEEP VALVE (cm H2O)	INSPIRATION TIME (s)	PEAK PRES. (cm H2O) (PIP)	MIN PRES. (cm H2O) (PEEP)	AVERAGE TIDAL VOLUME (mL)	TIDAL VOLUME (L) STDev	PERIODS CAPTURED (data points use in avg)
0.02	RP 5	200	15	15	1.00	33	21.2	200	17.0	18
0.04						32	20.1	190	16.0	
0.07						33	17.5	200	4.0	
0.02	RP 5	400	15	15	1.00	42	22.0	400	25.9	27
0.04						51	21.2	376	32.4	
0.07						46	18.6	393	20.8	
0.02	RP 5	600	15	15	1.00	59	18.5	623	23.0	12
0.04						52	13.0	621	8.4	
0.07						33	22.4	605	31.2	
0.02	RP 5	800	15	15	1.00	65	17.7	788	17.8	27
0.04						51	12.9	845	27.2	
0.07						50	22.3	790	14.1	



Patient Assist Performance Data

Animal testing description and results.

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